NATIONAL INSTITUTE OF SIDDHA

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY, CHENNAI - 32

PRECLINICAL AND CLINICAL STUDY ON

CEGANA VATHAM

AND THE DRUG OF CHOICE IS

KARIUPPU CHENDURAM

(DISSERTATION SUBJECT)

For the partial fulfillment of the

Requirements to the Degree of

DOCTOR OF MEDICINE (SIDDHA)

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INTRODUCTION

Siddha Medicine is not purely a medical system for curing the physical body, its a way of life formulated by Siddhars through their vision and realisation for getting peace for the mind, health, for the physical body and purity for the Soul.

Contemporary Tamil literature mentions the origin of the medical system from south India in the state tamilnadu as a part of trio Indian medicine ayurveda, siddha and unani. Reported to have surfaced more than 2500 years ago, the Siddha system of medicine is considered one of the most antiquated traditional medical systems. The siddha is floruished in the period of Indus valley civilization.

Siddha focussed to `Ashtamahasidddhi'that is the eight supernatural power, those who attained or achieved the above said power are known as siddhars.sage Agathiyar is considered as the guru of all siddhars.

Siddhars were of the concept that a healthy soul can only be developed through a healthy body, they wrote scripture on all aspects of life from arts of science and truth of life to miracle cure of diseases.

Siddha medicine is claimed to revitalize and rejuvenate dysfunctional organs that cause the disease and to maintaine the ratio of vatha, pitha and kabha.

It is assumed that when the normal equilibrium of the three humors is disturbed disease is caused.The factors that affect their equilibrium are environmental, climatic conditions,diet, physical activities and stress. Under normal conditions the ratio between the three humors are 4:2:1(Vatha, pitha and kabha respectively).

According to the Siddha medicine, various psychological and physiological functions of the body are attributed to the combination of seven elements: first is saram (plasma) responsible for growth, development and nourishment; second is cheneer (blood) responsible for nourishing muscles, imparting colour and improving intellect; the third is ooun (muscle) responsible for shape of the body; fourth is kollzuppu (fatty tissue) responsible for oil balance and lubricating joints; fifth is elumbu (bone) responsible for body structure and posture and movement; sixth is moolai (brain) responsible for strength; and the last is sukila (semen) responsible for reproduction. The physiological components of the human beings are classified as vata (air), pitta (fire) and kapha (earth and water).

Traumatological aspects have also been dealt in siddha system of medicine in the name of varmam.

The yogic techniques are very closely interwoven with the siddha system in all its manifestations

Thokkanam is a special kind of treatment in siddha system.It is of nine types. Solid research has proven that massage therapy can Sooth chronic joint and muscle pain.

In Siddha System, there are 80 types of vatha diseases, pitha is 40 types and kabha is 20types.

According to **yougi vaithiya sinthamani**

என்னவே வாதம் தான் எண்பதாகும்

CEGANAVATHAM is one among the 80 types of vatha disease. The symptomological description of the disease **CEGANAVATHAM** may be correlate to the symptoms of **CERVICAL SPONDYLOSIS**

Cervical spondylosis is defined as arthrosis of the posterior intervertebral joints in the cervical vertebrae. It is common in the middle aged and in the elderly particularly in those whose occupation involves a posture of prolonged neck flexion. The prevalence of the disease in 2011 is about 20- 25% of Population by the age of 50 Years & increases to 70 - 85% by the age of 65 Years.

The disease is more prevalent nowadays due to life style modifications . Pain in neck and other symptoms of the disease has impaired normal activity in our day today life. Cervical spondylosis is more common in the elderly where advanced changes leads to disabling pain and paresis.The etiology is thought to be related to ageing process and (or) mechanical overload applied to the spine.

The author's choices of medicines for clinical study are:

i.kariuppu chenduram-Internal medicine.

Ref:Anuboga Vaithiya Navaneetham part-3 by Hakeem B.M.Abdula Saib.(Thamarai Noolagam- Publications)

Dose – 260 mg twice daily with honey after food.

ii. kunthirika thylam – 50 ml (External medicine).

Ref: Pharmacopoeia of hospital of Indian medicine.

The medicines were prepared by the author in PG Gunapadam Laboratory, at National Institute Of Siddha under the guidance of the concerned Lecturers, and were tried in 10 selected IP cases and 30 selected OP cases of "Ceganavatham" of varied etiology and the clinical study was undertaken in the Maruthuvam dept.

A comprehensive knowledge of siddha and modern concept about etiology, signs and symptoms, pathology, and bio-chemical,toxicological and pharmacological analysis also discussed in this study.

AIM AND OBJECTIVES

AIM:

To document the siddha drug **Kariuppu Chenduram (internal) and kunthirika thylam(external)** in the treatment of **ceganavatham(cervical spondylosis)** by the standard process of evaluation of safety and efficacy of the drug.

OBJECTIVES

PRIMARY OBJECTIVE:

To evaluate the therapeutic efficacy of siddha drug **Kariuppu Chenduram (internal) and kunthirika thylam (external)** in the treatment of **ceganavatham(cervical spondylosis)**

SECONDARY OBJECTIVE:

1. To evaluate the safety profile (acute, long term toxicity studies) of this drug.

2. To study the effect of other co-factors such as age, sex and siddha parameters.

LITERATURE REVIEW
SIDDHA ASPECTS

In siddha literatures diseases are classified as 4448 types. Among 4448 types the vatha constitutes 84 types.

This mentioned as

நாளடா நாற்பத்து நாலு நூறு

நயமுடனே நாற்பத்து எட்டு ரோகம்

பாரப்பா வாதமது 84.

- இரத்தின சுருக்க நாடி நூல்.

According to Yugi Vaidhiya Chinthamani, Vadha is of 80 types.

என்னவே வாதம் தான் எண்பதாகும்

THE UYIR THATHUKKAL -THE THREE VITAL HUMORS:

Vatha,pitha and kabha are the three vital humors.The action of the three humors which is found essential for the chemical changes of blood and other thathus .Moreover the action of these three humors correspond to the Ahayam,vayu,fire,water,earth

respectively. when the normal equilibrium of the three humors is disturbed disease is caused

The relation between panchabootham and Uyir thathukkal

Uyir Thathukkal		**Panchabootham**
Vatham	_	Aahaayam (Space)
		Vayu (Air)
Pitham	_	Theyu (fire)
Kabam	_	Appu (Water)
		Prithivi (Earth)

The formation of Uyir Thathukkal,

மூவகை வாயுவும் உயிர் தாதுவும்

"உணர்ந்த அபானன் உறும் அந்த வாதத்தில்
புணர்ந்த பிராணன் புகும் அந்தப் பித்தத்தில்
அணைந்த சமானன் அடங்கும் கபத்தோடு
இணைந்திவை மூன்றுக்கு எடுத்த குறி ஒன்றே"

- பதிணென் சித்தர் நாடி சாஸ்திரம்

The Vali naadi is formed by the combination of Abanan and Idagalai.

The Azhal nadi is formed by combination of Piranan and Pinkalai.

The Iyya naadi is formed by combination of Samanan and Suzhumunai.

VATHA DISEASES

Geneis of Vadha

Vatha - **LOCATIONS:**

Below the navel.

"நாமென்ற வாதத்துக் கிருப்பிடமே கேளாய்

நாபிக்குக் கீழென்று நவில லாகும்." -யூகிமுனி

When vali bootham and Aakaya bootham are combined vadha is formed. Generally "Vatham" lives in,

1. Abaanan
2. Edakalai
3. Kamakodi
4. Undhiyin Keezh moolam
5. Hip region
6. Bones
7. Muscles
8. Nerves
9. Joints
10. Skin
11. Hair follicles and
12. Stools.

Physiologically “Vatham”, which has no alterations, lives in Gastro Intestinal Tract, Bones, Ear, Thigh, Hip and Skin.

According to vaidya chatakam, vatham dwells in the following places

Umbilicus,rectum,faecalmatters,abdomen,anus,bones,hib-joints,skin,navel plexus,joints,hair follicles and muscles.

அறிந்திடும் வாத மடங்கு மலத்தினில்
- திருமூலர்

According to saint Thirumoolar the place of vatham is anus.

FUNCTIONS OF VATHAM:

1. Body ache
2. Pricking pain
3. Tearing pain
4. Nerve weakness
5. Mental distress
6. Movements
7. Joints pain
8. Traumatic pain
9. Dislocation of joints
10. Weakness of organs
11. Paralysis of limbs
12. Polydypsia
13. Severe pain in calf and thigh muscles
14. Bony pricking pain
15. Anuria and constipation
16. Unable to do flexion and extension of the limbs
17. All tastes to be like astringent
18. Excess salivation.

Properties of vatham:

1.Helps in respiration

2.To activate the body,mind and the intellect.

3.To activate the fourteen natural reflexes.

4. To activate the seven physical constituents in junctional co-ordination.

5.To strengthen the five sense organs.

Qualities of vatham:

1.spreading

2.dryness

3.changing its place quickly

4.subtle

RELATION WITH TASTE

The tastes, which increase 'Vatham' are sour and astringent.

"புளிதுவர் விஞ்சுங்கறி யாற்பூரிக் கும்வாதம்

ஒளியுவர் கைப்பேறில் பித்துசீறும் - கிளிமொழியே

கார்ப்பினிப்பு விஞ்சிற்கபம் விஞ்சுஞ் சட்டிரதச்

சேரப் புணர் நோயணுகாதே" -நோய் நாடல்

The tastes, which neutralizes Vatham, are Sweet, Sour and Salt.

RELATION WITH FIVE ELEMENTS:

Vatham - Air + Sky.

The six tastes and their constituent elements are as follows.

1. Sweet = Earth + Water
2. Sour = Earth + Fire
3. Salt = Water + Fire
4. Bitter = Air + Sky
5. Pungent = Air + Fire
6. Astringent = Earth + Air

DESCRIPTION OF VATHAM:

The siddha classical texts divide the general principles of Vatham into ten subsidiary forms that differ from one another by their localizion in the body (Anatomical) and by their particular functions (Physioloical). They are

1. PRAANAN : (Heart Centre)

It maintains the action of the heart, the functioning of the mental faculties of perception and concentrations and also cares for the arteries, veins and nerves. It regulates the respiration and digestion. It is otherwise called as "Uyirkkaal".

2. ABAANAN (Moolaadharam Centre)

It controls the excretion. It is focussed in the lower part of the gut and also occupies the sites in the bladder and genitals. It has a tendency to travel downwards. It moves in the whole Genito Urinary Tract and regulates the defaecation, micturition, menstruation, parturition and ejaculation. It is otherwise termed as "Kezhnokkumkaal".

3. VIYAANAN: (Fore head Centre)

It helps in the circulation of energy throughout the entire nervous system and the movements of various parts of the body. It also transports nutrients and blood throughout the entire body. It is also known as "Paravukaal."

4. UDHAANAN: (Throat Centre)

It controls speech and breathing. It is also responsible for the physiological reflex actions like vomiting, hiccup, cough, etc., It has the tendency to travel upwards. It is otherwise named as "Melnokkukaal."

5. SAMAANAN: (Navel Centre)

It corresponds to the solar plexus in the navel region and controls digestion. It selects the useful substances from the swallowed food and supplies them to the whole body. It balances the other 'Vayus" it is also called "Nadukkaal."

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6. NAAGAN:

It is responsible for the intelligence of an individual, winking, singing and pilo erection.

7. KOORMAN:

It is responsible for yawning, closing of mouth (immovable of lower jaw) winking, shedding of tears, vision and opening of the eyes.

8. KIRUGARAN:

It is responsible for salivation and nasal secretion. It helps in digestion and meditation. It produces cough and sneeze.

9. DHEVATHATHAN:

It is responsible for laziness, lassitude, to quarreling arguing, begging and also for much anger. It helps movements of the eyeball in various directions and is present in genital and anal region.

10. THANANJEYAN:

It is present in nose and responsible for swelling of the body and tinnitus. It leaves from the body by blowing up the cranium only on the third day after death.

FEATURES OF INCREASED OF VATHAM:

1.person is physically weak emaciated,dark in complextion.

2.Desired towards hot food stuffs

3Presence of tremors

4.Distended abdomen

5.Constipation

6.Reduction in strength

7.Insomnia

8Diminished activities of five sense organs

9.Blabbering speech

10. Vertigo

11.Loss of perseverance.

FEATURES OF DECREASED VATHAM

1.Body pain

2.feeble voice

3.decreased activities

4.dull mental power

5.Episodes of syncope

உணவுவகைகள் (Diet which induce vatham)

A. Quotes under Sababathi Kaiyedu :

"வளி தரு காய்கிழங்கு வரைவிலா தயிலல் கோழை
புளி தயிர் போன்மிகுக்கு முறையிலா வுண்டி கோடல்
குளிர்தரு வளியிற் றேகங் குனிப்புற வுலவல் பெண்டிர்
குளிதரு மயக்கம் பெற்றோர் கடிசெயல் கருவியாமல்."

-சபாபதி கையேடு

According to Sababathi Kaiyedu, increased intake of tubers, increased exposure to wind, living in higher altitudes, increased sexual desire, increased exposure to chill weather will aggravate Vali diseases.

. **Quotes under Pararasa sekaram**,

"தொழில் பெறு கைப்புக்கார்த்தல் துவர்த்தல் விஞ்சுகினுஞ்சோறும்
பழையதாம் வரகு மற்றைப் பைந்தினையருந்தினாலும்
எழில் பெறப் பகலுறங்கி இரவினிலுறங்காதாலும்
மழை நிகா குழலினாலே வாதங்கோ பிக்குங்காணே.

- பரராச சேகரம்

According to Pararasa Sekeram, increased intake of bitter taste, astringents, sour tastes, increased intake of old cooked rice, intake of grains, day slumber and staying back at night will increase Vali.

SEASONAL VARIATIONS OF VATHAM:

Vatham aggravates in its own place in summer,influences other humors in monsoon season and is normal in spring.

In summer due to seasonal variations all the useful plants and human body gets dry.the vatham as such though it should have a different state of growth due to its own heat. Vatha kuttram attains thannilai valarchi (mild derangement) during mudhuvenil kaalam and vetrunilai valarchi (much derangement) during Kaar kaalam

THINAIGAL:

Nilam is classified into five types. They are,

1. Kurinji	:	Mountain and its surroundings. Kabanoigal and liver diseases are common
2. Mullai	:	Forest and its surroundings, pitha noigal, vatha noigal, liver diseases are common
3. Marutham	:	Field and its surroundings safest place to maintain good health.
4. Neidhal	:	Sea and its surrounding**, Vatha diseases** and liver enlargements are common.
5. Paalai	:	Desert and its surroundings**, Vatha, Pitha and kaba noigal are common.**

CLASSIFICATION OF VATHA DISEASES:

Various siddha texts gives different classifications of Vatha diseases as follows:

SI.No.	Name of the siddha Test	Types
1.	Agasthiyar -2000 எண்பது வாதமாகு மிருவகைப்படுத்திக் காணின் நண்புறு அரைக்குமேலே நாற்பது வாதமாகும் பண்சேரரைக்குக் கீழே பத்து நான்காகுமென்று வண்டுசேர் குழலினாளே வாதத்தின் கூறுதானே	80
2.	Agasthiyar Gurunaadi – 235	84
3.	Agasthiyar Rathina Surukkam – 500 "மற்றமே வாதரோகம் வகை எண்பத்து நாலே"	84
4.	Ashtaanga Sangiragam	85
5. Bohar Vaidhiyam – 700 "வாச்சென்ற வாதம் எண்பதுவும் போகும்"		80
6. Jeeva Rakshaamirdham		80
7. Noi Naadal and Noi Mudhal Naadal – part II		85
8. Thanvandhiri Vaidhiyam		80
9. Theraiyar Vaagadam		81
10. Yogi Vaidhya Sindhaamani Perunool – 800 "என்னவே வாதமது எண்பதாகும்"		80
11. Yogai Vaidhya Sindhaamani Perunool -800 "ஆமப்பா வாதம் மெண்பத்து நாலு அதனுடைய குணா குணங்க லடங்கலாக"		84

CLINICAL FEATURES:

The signs and symptoms of Vatha diseases have been Mentioned in various siddha classical text books they are as follows **Agasthiyar Naadi:**

"சொல்லவே வாத மது மீறிற்றால்

சோர்வடைந்த வாயு வினால் தேகமெங்கும்

மேல்ல கைகால் அசதி யுண்டாகும்

மேய்முடங்கும் நிமிரவொண்ணாத் திமிர் உண்டாகும்"

- அகத்தியர் நாடி

1. Weakness of the limbs
2. Sluggishness,
3. Stiffness

In Agasthiyar - 2000

"வாதத்தின் குணமேதென்னில் மயக்குந்தியெங்கும் மலர்சிவக்கும்

பாதங்குளிர்ந்து சருவாங்கம்பற்றி நடக்குமுகங் கடுக்குஞ்

சீதத்துடனே வயிறுபுண்ணாஞ் சிரிப்பித் ததுந்தெறி மூச்சாம்

போதத் தண்ணீர்தான் வாங்கும் புகழும் பஞ்ச குணமாமே"

1. Giddiness
2. Stabbing pain in the face
3. Redness of eyes
4. Peptic Ulcer
5. Abdominal distension
6. Joint pain in upper and lower limbs
7. Numbness in the limbs
8. Oliguria,
9. Drowsiness and
10. Chillness of body

Naadi:

The naadi can be felt one inch below the wrist on the radial side by means of palpation and percussion with the tip of the index, middle and ring finger corresponding of Vatham, Pitham and Kabam respectively. The three humours exist in the ratio of 1:1/2:1/4 normally. Derangement of this ratio leads to various diseases.

In cases of **vatha diseases** the following stages of Naadi are seen

1. "வாதமெனும் நாடியது தோன்றில்
   சீதந்தமொடு வயிறு பொருமல் திரட்சிவாயு

   சீதமுறுங் கிராணி மகோதரம் நீராமை

   திரள்வாயு சூலைவலி கடுப்புத் திரை"

- சதகநாடி

2. "சொல்லவே வாதமது மீறிற்றானால்

   சோர்வடைந்த வாயுவினால் தேகமெங்கும்

   மெல்ல கைகால் களசதியுண்டாகும்

   மெய்முடங்க நிமிரவொண்ணாத் திமிருண்டாகும்"

- அகத்தியர் நாடி

"காணப்பா வாதமீறில் கால்கைகள் பொருந்தி நோகும்"

- காவிய நாடி.

Vatha Pitha Naadi

"பொருளான வாதத்தில் பித்தஞ் சேர்ந்து

கருவான தேகமதிலுளைச்சல் சோம்பல்

கைகால் தறிப்'"

""""ஊன் குறைதல்

- சதகநாடி

"திருத்தமாம் வாதத்தோடே தீங்கொடு பித்தஞ் சேரிற்

பொருந்துகள் தோறும் நொந்து போதவே பிடிக்கும்"

- நோயின் சாரம்

Vatha Kaba Naadi

"பாங்கான வாதத்தில் சேத்தும நாடி

பரிசித்தால் திமிர்மேவு முளைச்சலாகும்"

- சதகநாடி

"வாதத்தில் சேத்துமமாகில் வலியோடு வீக்கமுண்டாம்"

- அகத்தியர் நாடி

Pitha Vatha Naadi

"பித்தத்தில் வாதமாகில் பிடரியுங் காலுங் கையுங்

குத்தது போலேயாகுங் குறுகி மெய்பதறும் பின்னே"

- அகத்தியர் நாடி

Pitha kaba Naadi

"பித்தத்தில் சேத்துமமாகில் வாய்குளறுமிகக

பித்தமுமெடுத்துக் கொட்டிப் பிடரியில் நோவதாமே"

- அகத்தியர் நாடி

Kaba Vatha Naadi

"கணடாயோ சிலேற்பனத்தில் வாதநாடி
கலந்திடுகில் வயிறுபொருமல் கனத்தவீககம்

உண்டாலோ ஓங்காரஞ் சத்தி விக்கல்

உறுத்திரட்சை வாய்வுவலி சன்னிதோடம்"**- சதகநாடி**

In all Cegana vatham patients Vatha, Pitha, Thondha naadi was noted.

CEGANA VATHAM

DEFINITION:

Ceganavatham is one of the vatha disease described in **'Yugi Vaidhya Sindhamani - 800'.** It is a condition dealing with the involvement of the neck which is identical to the cervical spine, comprising the symptoms of pain in the nape of the neck, radiating pain in the upper limbs, feeling of heaviness in the body, mental depression, giddiness, burning sensation of the eyes and constipation.

Aetiology:

The common aetiological factors for all types of Vatha diseases including "Ceganavatham" have been described generally in Yoogi Vaidhya Sindhamani -800, Agasthiyar kanma kaandam – 300 and Agastthiyar Gunavagadam

1**. In Agasthiyar Gunavagadam,**

"தொல்லை செய்ய இன்னும்வெகு வாதநோய்கள்
தொல்லுலகில் மாந்தருக்குக் காண்பதுண்டு
எல்லையில்லை வாதநோய் நேர்மைதன்னை
இயல்பாக அறிந்திடவே விபரங் கேளே"

"விவரமடா அசதிசன்னி மூளை நோவு
விரிவான மூளையது மிருதுவாகி
இவனிதனில் திடமாகப் போவதாலும்
அப்பனே மூத்திரக் குண்டிக்காய் வியாதியாலும்
தவமுனிவர் தீர்காக்கை மேகரோகம்
தன்மையுள்ள முத்தண்டுக் கொடி வியாதி
அவமிலாப் பரிச நரம்பழுத்தங்கண்டாய;
அணுகுமடா வாதநோய் ஆகும்பாரே".

"அணுகுமடா மாமிசத்தின் வியாதியாலும்

அப்பனே சூதகத்தின் பெருக்காலும்

குணமில்லா இரசம் வங்கம் தின்னலாலும்

குடிகெடுத்த வாதமது உண்டாமப்பா"

-அகஸ்தியர் குணவாகடம்

1. Diseases of brain

2. Renal disorders

3. Sexually transmitted disease

4. Disease of the vertebral column and spinal cord

5. Menorrhogia

6. Taking improperly prepared medicines of mercury and lead will cause Vatha disease.

In Agasthiyar Kanma kaandam -300,

"நூலென்ற வாதம் வந்தவகை தானேது

துண்மையாய்க் கன்மத்தின் வகையைக் கேளு

காலிலே தோன்றியது கடுப்ப தேது

கைகாலில் முடக்கியது வீக்கமேது

கோலிலே படுகின்ற விருட்ச மான

குழந்தை மரந்தன்னை வெட்டல்மேல் தோல்சீவல்

நாலிலே சீவசெந்து கால் முறித்தால்

நல்ல கொண்பு தழை முறித்தல் நலித்தல் தானே"

-பாடல் 56

1. Cutting the trees
2. Breaking the legs of living animals
3. Cutting the branches and leaves of living trees

In **Yoogi Vaidhya Sindhaamani,** the following causes are given as follows:

"தானென்ற கசப்போடு துவர்ப் புறைப்பு
சாதகமாய் மிஞ்சுகிலும் சமைத்த வண்ணம்
ஆனென்ற வாறினது புசித்த லாலும்
ஆகாயத் தேறலது குடித்தாலாலும்
பானென்ற பகலுறக்க மிராவிழிப்பு
பட்டினியே மிகவுறுதல் பார மெய்தல்
தேனென்ற மொழியார் மேற்சிந்தை யாதல்
சீக்கிரமாய் வாதமது செனிக்குந் தானே"

-பாடல் 244

"பகரவே வாதமது கோபித் தப்போ
பண்பாக பெண்போக மதுதான் செய்யில்
நகரவே வெகுதூர வழி நடக்கில்
நளிரான காற்றுமே பனிமேற் பட்டால்
மிகரவே காய்கள் கனிகிழங்கு தன்னை
மிகவருந்தி மீறியே தயிர்தான் கொண்டால்
முகரவே முதுகெலும்பை முறுக்கி நொந்து
முழங்காலும் கணைக்காலும் கடுப்பு உண்டாமே"

- பாடல் 285

1. Consumption of bitter, astringents and pungent taste foods excessively.
2. Eating previously cooked food
3. Drinking polluted water
4. Changing sleep rhythm
5. Excessive starvation
6. Lifting heavy objects
7. Excessive lust
8. Walking long distance
9. Living in chill environment
10. Excessive consumption of tubers, fruits, curd etc.

Kanma Vinai is also implicated in the aetiology of Vatham.

The aetiological factors are as follows,

"நூலென்ற வாதம் வந்தவகை தானேது
துன்மையாய்க் கன்மத்தின் வகையைக் கேளே
காலிலே தோன்றியது கடுப்ப தேது
கைகாலில் முடக்கியது வீக்கமேது
கோலிலே படுகின்ற விருட்ச மான
குழந்தை மரந்தன்னை வெட்டல்மேல் தோல்சீவல்
நாலிலே சீவசெந்து கால் முறித்தல்
நல்ல கொண்பு தழை முறித்தல் நலித்தல் தானே"

-அகத்தியர் கன்ம காண்டம்

"என்னவே வாதந்தா னெண்பதாகும்
இகத்திலே மனிதர்களுக் கெய்யுமாறு
பின்னவே பொன்னதனையே சோரஞ்செய்து
பெரியோர்கள் பிராமணரைத் தூடனித்தும்
வன்ன தேவச் சொத்தில் சோரஞ்செய்து

மாதாபிதா குருவை மறந்த பேர்க்கும்

கன்னவே நிந்தை செய்தால்

காயத்திற் கலந்திடுமே வாதந்தானே”

-யூகி வைத்திய சிந்தாமணி 800

“ஆனான வரன்றனையே மதியாமாந்தர்

அகதி பரதேசியர்கட் கன்ன மீயார்

கோனான குருமொழியை மறந்த பேர்கள்

கொலை களவு பொய்காமங் குறித்த பேர்க்கு

ஊனான சடந்தன்னில் வாதம் வந்து

உற்பவிக்கும் வேதத்தின் உண்மைதானே”

-யூகி வைத்திய சிந்தாமணி 800

1. Cutting trees, tree bark, tender leaves
2. Breach of trust
3. Abusing elderly and priest
4. Exploitation of charitable properties
5. Ingratitude with mother, father and guru
6. Irrespectful attitude with god
7. Refusing food for destitutes and hermits
8. Involvement in murder theft, lustfull activities

In **Agasthiyar Gunavagadam** the following causes are given,

“தன்மையள்ள முத்தண்டுக் கொடி வியாதி

அவமிலாப் பரிசு நரம்பழுத்தங் கண்டாய்

அணுகுமடா வாதநோய் ஆகும்பாரே

அணுகுமடா மாமிசத்தின் வியாதியாலும்

அப்பனே சூதகத்தின் பெருக்காலும்

குணமில்லா இரசம் வங்கம் தின்னலாலும்

குடிகெடுத்த வாதமது உண்டாமப்பா”

- அகத்தியர் கன்ம காண்டம்

1. Diseases of the vertebral column and spinal cord

2. Diseases of muscles

3. Menorrhogia

4. Mercury poisoning

5. Lead poisoning

6. Taking im-properly prepared medicines of mercury and lead will cause Vatha disease.

CLINICAL FEATURES:

The signs and symptoms of Cegana vatham described in **Yoogi Vaithya Sinthamani** and **Pararasasekaram** by the following verses.

"கேளுமே கழுத்தின் கீழரைக்கு மேலும்

கெடியான கரமிரண்டு மிகவே நொந்து

வாளுமே சரீரமெல்லாங் கனத்திருக்கும்

வாலிபர்க்கு மனங்கண்ணு மயக்கமாகும்

ஏளுமே இரண்டு கண்ணும் எரிச்சலுண்டாம்

ஏற்றமாய் மலந் தானும் இறுகிக் காணும்
தேளுமே கொட்டினது போற் கடுக்கும்

சேகனவளி நோயினூட தீர்க்கந்தானே"

-யூகி வைத்திய சிந்தாமணி

"கண்டதோர் சிகன்ன வாதங் கழுத்தின் கீழரைக்கு மேலும்

மிண்டலங் கரமிரண்டு மிக நொந்து கனத்திருக்கும்

மண்டியே திமிர்த்துக் குத்தும் வலி மிகுத்துளைவுண்டாகும்

வண்டமர் குழலினாளே மதியினாலுன்னுவாயே"

-பரராசசேகரம்

1. Pain in the neck

2. Radiating pain to the shoulders and upper limb

3. Heaviness of the body

4. Mental depression

5. Giddiness

6. Burning sensation of the eyes

7. Constipation

8. Pain like scorpion sting

9. Tingling sensation and numbness of the upper limbs.

En vagai thervu

" நாடிப் பரிசம் நா நிறம் மொழி விழி

மலம் மூத்திரமிவை மருத்துவராயுதம்"

- தேரையர்

1. Naadi

2. Sparisam

3. Naa

4. Niram

5. Mozhi

6. Vizhi

7. Malam

8. Moothiram

Naadi:

Naadi means a vital force responsible for birth *(- Agathiyar*)

This vital force is divided into three humours, vatham, pitham and kabam. It can be assessed in 10 sites. The commonest site is wrist (over radial artery).

In **ceganavatham,**

Vathapitham

“பொருளான வாதத்தில் பித்தஞ்சேர்ந்து

கைகால் தறிப்பு நாகசக்குமன்னம்”

- சதக நாடி

Pithavatham

“பித்தத்தில் வாதமாகில் பிடரியும் காலும் கையும் குத்தது போலே யாகுங் குறுகி மெய்பதுறும் பின்னே”

Sparism:

By sparisam the temperature of the skin, smoothness of roughness, sweat, dryness, hard patches, swelling, abnormal growth, tenderness and nourishment can be felt.

In Ceganavatham there was tenderness in the cervical region for all the patients.

Naa:

Examination of the tongue for its colour, coating dryness, deviation, sensory changes, ulcer, conditions of the tooth and gums are noted for all the ceganavatham patients.

Niram:

Colour indicating vatha, pitha, kaba and thridhosas. Yellow or pallor or redness of the skin, bluish discolouration of the face, conjunctiva can be noted. There was no specific abnormality in niram of ceganavatham cases.

Mozhi:

Clarity of speech, or any disturbance, loud voice, slurring, crying, talks induced by hallucination, undue argument can be made out.

Mozhi was normal in all Cegana vatham cases.

Vizhi

Testing for acuity of vision, colour, redness, pallor, whiteness, burning sensation, excessive lacrimation.

Burning sensation of the eyes is present. In aged patients acuity of vision is diminished in ceganavatham.

Malam

The faeces should be semi- solid without hardness and looseness.

Nature, quantity, colour, odour, froth, presence of blood and mucous are noted.Some Patients have constipation.

Moothiram

The urine is examined by neerkuri and neikuri.

Some patients have oliguria.

In Siddha system of medicine, besides Ennvagai thervugal, a disease can be diagnosed by means of Kanmendhiriyam, Gnannendhiriyam Uyir thaathukkal, Udal thaathukkal, Thinaigal and Paruva kalangal.

1. Gnaanendhiriyam:

The five Gnaanendhiriyam are

1. Mei - Feels all types of sensations
2. Vaai - For taste
3. Kan - For vision
4. Mookku - For smell
5. Sevi - For hearing

In ceganavatham patients mei is affected in all cases.In some persons kan is affected due to age condition.

Kanmendhiriyam:

1. Kai - Works done by the hands
2. Kaal - For walking
3. Vaai - For speaking
4. Eruvai - For defaecation
5. Karuvai - For reproduction

In ceganavatham kai is affected i.e., pain and numbness along both upper limbs presents.

3. Uyir Thaathukkal:

1. Vatham:

In Ceganavatham the following Vayus are affected.

a) Viyanan:

Neck pain, restricted movement of neck, radiating pain in the shoulders, and upper limbs, tingling sensation, numbness and giddiness.

b) Abanan:

Constipation

c) Samanan:

Indigestion, imbalance in the functions of other vayu.

d) Udhanan:

cough

e) Naagan:

Sluggishness, mental depression

f) Devathathan:

Sleeplessness

PITHAM:

Pitham is located in Urinary bladder, Heart, Head, Umbilicus, pinkalai, Piraana, Abdomen, Stomach, Sweat, Blood, Eye and skin. It is classified into five types they are

1. Anar pitham : It digests all the ingested food particles

2. Ranjaga pitham : It gives colour to the blood

3. Saadhaga pitham : It is used to complete the work properly what we think in our mind.

4. Alosaga pitham : It gives vision to the eye

5. Piraasaga pitham : It gives colour to the skin.

Saadhaga pitham is commonly affected in Cegana vatham.

KABHAM:

Kabham is located in Samaanan, Semen, Fat, Bone marrow, Nose, Chest, Nerves, Bones, Brain, Large intestine, Stomach and pancreas. It is divided into five types. They are

1. Avalambagam : It controls the other four types of kabham
2. Kiledhagam : It moistens the food
3. Podhagam : It helps to know the taste
4. Tharpagam : It gives cooling effect to the eyes.
5. Sandhigam : It gives lubrication effect to the joints

In Cegana Vatham Tharpagam and Sandhigam are affected.

Noi Kanippu Vivaadham (Differential Diagnosis)

Some other types of Vatha diseases resembling the symptoms of Cegana vatham are mentioned. Careful and clear history taking and examination will reveal the diagnosis. They are,

1. Kanda Kiraga Vatham
2. Kumba Vatham
3. Paanikamba Vatham
4. Pei Vatham
5. Sirakamba Vatham

1. Kanda Kiraga Vatham:

"வகையான குரலதனைப் பற்றி நொந்து

மார்போடு பிடரிதனில் வலியுண்டாகி

நுகரான சரீரமெல்லாம் நொந்த ழாற்றி

நுணக்கமாய் சுவாசமது புறப்ப டாமல்

முகையான நாவாலே மூச்சு மாறி

முகத்திலே வியர்வாகி விலாநோ வுண்டாம்

புகையான வன்னத்தைப் பருகொட்டாது

புரிய கண்ட கிராகத்தின் பண்பு தானே".

-யூகி வைத்திய சிந்தாமணி - 800

The Clinical features are,

1. Pain in the throat, chest and occipital region
2. Anorexia
3. Breathing through mouth
4. Backache
5. Sweating on face

2.Kumba Vatham:

"நலிலவே தோள்மீதும் கரத்தின் மீது

நலிந்து மெத்த வாகியே நசவுண்டாகும்

கவிலவே கன்னமொடு நயனந்தானுமங்

கடுத்துமே விறுவிறுப்பு மெரிவும் காணும்

துவிலவே துடிப்பாகும் சிரசு தன்னிற்

சுழற்றியே நாபிக்கீழ் வலியு முண்டாகும்

அவிலவே அடிநாக்கி லழன்று காணு

மலருமே வருகும்ப வாதந்தானே"

-யூகி வைத்திய சிந்தாமணி -800.

The clinical features are,

1.Burning pain in shoulder and upper limbs

2.Burning sensation in the cheek and eyes

3.Twitching over the scalp

4.Pain in the lower abdomen

5.Glossitis.

2. Paanikamba Vatham:

"மார்க்கமாய் வாய்வு மாய் மெய்நி றைந்து

வயிறுதனிற் பசியிலா தூணு மற்று

நார்க்கமாய் ஞாலத்து நடக்கை யற்று

நடுக்கமர் கையிரண்டுந் திமிரு முண்டாம்

ஊர்க்கமா யுறக்கமில்லா துணர்ச்சி யற்று

உதறியே சரீரம் எங்கு முலர்ந்து காணும்

பார்க்கமாய் வாய்விட்டு அலத்த லாகும்

பாணிக் கம்பவாத்தின் பாங்குதானே"-யூகி வைத்திய சிந்தாமணி -800

The clinical features are,

1. Anorexia
2. Tingling sensation and numbness of upperlimbs
3. Tremor of upper limbs
4. Sleeplessness and
5. Dryness all over the body

3. Peivatham:

”பெற்றியாம பெருமையாங் காலும் கையும்

பெருவயிறு நெஞ்சோடு விரலு மூக்கும்

ஏற்றியா மெறிகபுத்து மெங்கும் பற்றி

ஏக்கமாய் நொந் துடும் பெங்கும் வீங்கி

ஊற்றியா முணவே திமிர்த் தெடுத்து

உறுதியாய்ப பிடிக்கவு மொணாம லாகுந்

சத்தியாய் வாய்கசந்து மயக்க மாகுந்

தரித்திட வொண்ணாது பேய் வாதந் தானே”.

-யூகி வைத்திய சிந்தாமணி - 800.

The clinical features are,

1. pain and swelling in neck, upper and lower limb
2. Weakness of hand muscles, difficulty in holding things in the hand
3. Vomiting
4. Giddiness and
5. Swelling all over the body.

5. **Sirakamba Vatham:**

"தம்பமாய் உதிரகண்ட நரம்பிற் புக்கித்

தலையோடு சரீரமெலாந் தாக்கிப் புக்கும்

கம்பமாங் காதிரண்டு மிகுவுங் கேளா

கையோடு காலிரண்டும் வசக் கேடாகும்

நிம்பமாய் நினைவு தான் கலங்கிக் காணும்

நெடு மூச்சுங் கொட்டாவி நித்திரை யாகும்

சிம்பமாய் தலைநடுங்கிக் கனப்பு முண்டாஞ்

சிரக்கம்ப வாத மென்றே செப்பலாமே".

-யூகி வைத்திய சிந்தாமணி -800.

The main clinical features are,

1. Stiffness of neck
2. Deafness
3. Yawning
4. Over sleeping
5. Tremor in the head and neck
6. Difficulty in using lower and upper limbs

LINE OF TREATMENT:

In Siddha system the treatment is mainly based upon the Mukkuttram principle. Treatment is not only for perfect cure but also for the prevention of diseases and rejuvenation of udal kattukkal. The physician's duty is to diagnose the disease, trace the etiology and choose proper line of treatment.

The management of the disease in Siddha is as follows,

1. **Neekkam(treatment)**
2. **Niraivu(restoration)**
3. **Kaappu(prevention)**

After occurrence of the disease, first it should be treated, restoration should be done and recurrence or further complications should be prevented.

1. NEEKKAM:

Nekkam is based on,

- Balancing deranged thodams to normal equilibrium state.
- Treating with internal medicine and external medicine.
- Deranged vatham has to be brought to its normal state by giving purgation. It is mentioned in the following verses,

"விரேசனத்தால் வாதம் தாழும்"

-சித்த மருத்துவாங்க சுருக்கம்

Purgative:

Agasthiyar kuzhambu – 130mg given with ginger juice in early morning (for the first day only)

Internal medicine:

Kariuppu chenduram-260mg bd with honey , for 48 days(.Anuboga vaithiya navaneeetham part-3) **Pg.no 36,37,2nd Edition:2001**

External medicine:

Kunthirika thailam (Pharmacopoeia of hospital of indian medicine Pg.no:133,2nd edition 1995)

Diet Restrictions:

Mustard, sesame oil, pumpkin, garlic, asafoetida, bengal gram, horse gram, sesbania, bitter guard, coconut, mango and jack fruit should be avoided by patients with vatha diseases.Sour and astringent diet should be avoided as it will increase vatham.

"கடுகு நற்றிலத் தெண்ணெய் கூழ்பாண்டங்கள் கடலை
வடுவதாகிய தெங்குமா வருக்கை நற்காயம்
மடிவிலாத வெள்ளுள்ளி கொள் புகையிலை மதுபெண்
மிடறு பாகலோ டகத்தி நீக்கிடலிச்சா பத்தியம்"

- சித்த மருத்துவாங்க சுருக்கம்

"புளிதுவர் விஞ்சு கறியால் பூரிக்கும் வாதம்"

- நோய்நாடல் நோய்முதல் நாடல் திரட்டு

2. NIRAIVU:

The patient is convinced to accept the eventuality of the disease and modification of life style.

"ஒன்றிய வாதபித்த கபமிவை யுயரா வண்ணம்
நன்றுறு கறிகளெல்லாம் நாளுமே சமைப்பாராய்ந்தோர்
தின்றிடு மிளகு மஞ்சள் சீரக முயர்ந்த காயம்
வென்றி கொள் சுக்கோடேலம் வெந்தயம் உள்ளி சேர்த்தே"

- *நோயில்லா நெறி*

To maintain normal level of three humours, pepper, turmeric, cumin seeds, asafoetida, dry ginger, cardamom, fenugreek and garlic should be added generously in diet.

3. KAAPPU:

Siddha system prominently projects prevention of diseases. This is attained by the following methods,

1. Maintaining equilibrium of three humors by adopting vaanthi, kazhichal, nasiyam, nei muzhukku techniques.
2. Avoiding stress and strain.
3. Maintaining good mental health by doing meditation.

In Ceganavatham, pain in neck, radiating pain in shoulder, upper limbs, and numbness can be reduced by manipulating the following varmam points,

- Muduchi
- Kakkattai kaalam
- Manibanthagam
- Savvu
- Kavuli

Referance: Shanmugam Asan Methodology.

Exercises /asanas advised for Cegana vatham :

1). Neck Bending

a).Starting Position

- Sit with both legs straight.
- Place the palms on the floor by the side of the buttocks
- Keep the back, neck and head straight
- Close the eyes
- This is Dandasana

b) Practice

Stage - I (Forward – Backward movement).

- Slowly move the head forward and try to touch the chin to chest.
- Then move the head as far back as comfortable.
- Try to feel the stretch of the muscles in front and back of the neck and the loosening of the spine in the neck.
- Practice 10 times.
- Inhale on the backward movement and exhale on the forward movement.

Stage –II (Bending to Right and Left)

- Close the eyes and face directly forward.
- Slowly bend the head to the right and ear coming to the shoulder turning the head or lifting the shoulder.
- Bring the head back to the normal position
- Then bend in to the left side and try to touch the left ear to the left shoulder in the same fashion. Lift the head to the centre
- This is one round. Practice 10 rounds
- Inhale on the upward movement and exhale on the downward movement.

Stage –III (Turing the head to Right and Left)

- Keep the head upright and eyes closed.
- Gently turn the head to the right so that the chin is in line with the shoulder.
- Slowly turn the head to the left through the centre till the chin is in line with the shoulder. Bring the head to centre.
- This is one round. Practice 10 rounds.
- Inhale while turning to the front. Exhale while turning to sides.

c) Note : (For all the three stages)

- Move the head as far as comfortable. Do not strain
- Keep the shoulders relaxed and unmoved
- Feel the release of tension in the neck muscles and the shoulder muscles.

Contra - Indications

- Should not be performed extreme positions by elderly people
- Cervical spondylosis cases to avoid during acute pain

Benefits

- Theses asanas release tension (accumulated especially after prolonged work at a desk), and also heaviness and stiffness in the head, neck and shoulder region.

Additional points to Note

- Make the movements cautiously and slowly when there is Neck pain.
- Practice them with normal breathing
- Hold the neck in the final positions for a few moments
- If you have pain at any stage, stop in that position for a while. As you bring your complete awareness to the area of pain, start breathing consciously and deeply, then continue the movement.
- It can be practiced even while standing in Tadasana or sitting on a chair, or in Vajrasana.

2.Neck Rotation

a) Starting Position

- Sit in Dandasana

b) Practice

Stage –I (Half Rotation)

- Relax the head bending forward
- Bring the right ear to the right shoulder in a circular way.
- Bring the left ear to the left shoulder in a circular bending the head forward.

Now relax the head forward again in a circular way and finally lift the head to normal position. This is one round.

Repeat 10 rounds clockwise and 10 rounds anti – clockwise with breathing.

Stage -11 (Full Rotation)

- Relax the head forward trying to touch the chin to the chest.
- Slowly rotate the head in as large a circle as possible, keeping the chin tucked in.
- Practice 10 rounds clockwise and 10 rounds anti- clockwise while breathing normally.

1. **Note**

- In both cases (Half and full Rotations) you may take about one minute or even longer for one cycle. Allow normal breathing without trying to synchronise the breath & neck movements.
- In full rotation, try to make the circle bigger and bigger.
- Keep the eyes closed throughout the practice
- Feel the shifting stretch around the neck and loosening up of the joints and muscles of the neck.
- Practice full rotation very carefully. Start with half rotation and then go for full rotation.
- If there is pain in any position, hold the head in that position. Become aware of the point or area of pain and start breathing consciously and deeply. This will relieve you of pain and then you can continue.
- Can be practiced in cross – legged sitting position, or sitting on a chair.

Contra - indications

- Should be performed carefully by elderly people
- Cervical spondylosis cases to avoid during acute pain

Benefits

- Theses practices release tension (accumulated especially after prolonged work at a desk), and also heaviness and stiffness in the head, neck and shoulder region.

IV) Thokkanam (Massage Theraphy)

Thokkanam is systemic manupulation of the body parts by the physician.

"தொக்கணத்தினாலிரத்தம் தோல் ஊனிவை கட்கு
மிக்க சவுக்கியம் சமீரனும் போம் - மெய்க்கதிக
புட்டியுறக்கம் புணர்ச்சி யிவை கதிக்கும்
பட்ட அலைச்சலறும் பார்"

-பதார்த்த குணசிந்தாமணி

Thokkanam acts directly on vascular system, nervous sytem, lymphatic system and musculo – skeletal system and brings the affected body to normal condition physically and mentally. It also gives a sense of well being, gives a good sleep and increases vital power and also provides relaxation.

Vatha diseases are relieved specially by thokkanam. The following verse reveals that,

"மத்தனமாகிய தொக்கணத்தின் செயல் வகுப்பானே - சதா
நித்தமும் வாதம் பிணித்த பிணிப்பை செகுப்பேனே".

- தேரையர் மகா கரிசல்

Among the nine types of Thokkanam, only two must be done in the case of Sagana vatham.

1. Pidiththal (Effleurage and petriassage)

2. Izhuththal (Traction)

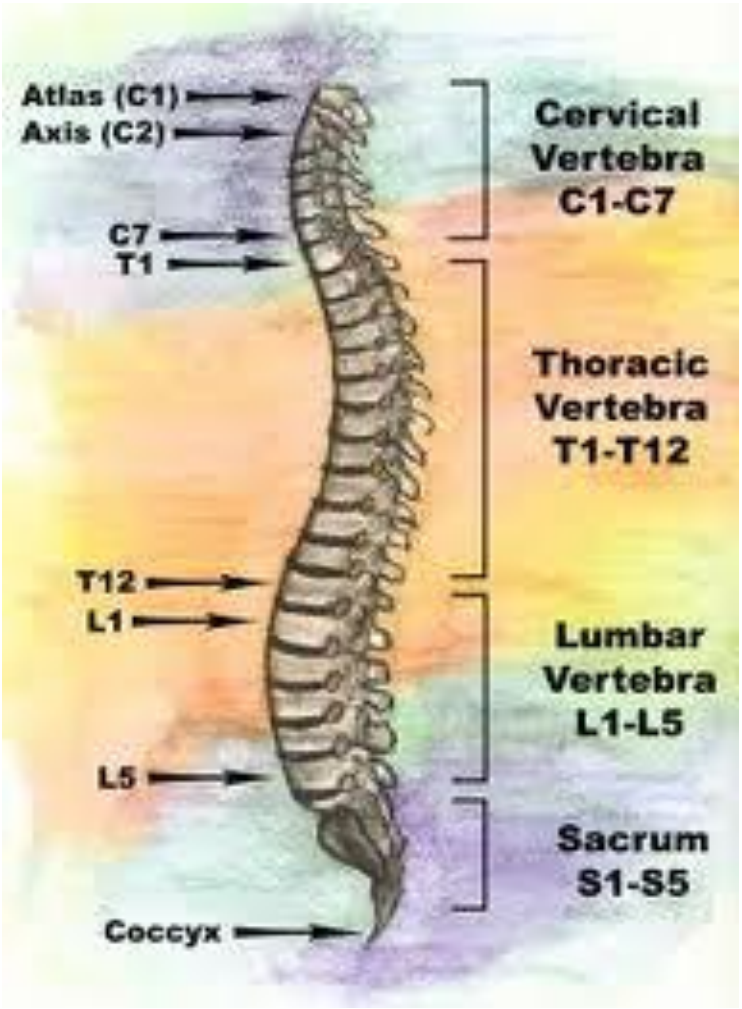
In pidiththal, Strokes are slided smoothly and by kneeing and in Izhuththal, traction like method is performed.

MODERN ASPECT

THE ANATOMY

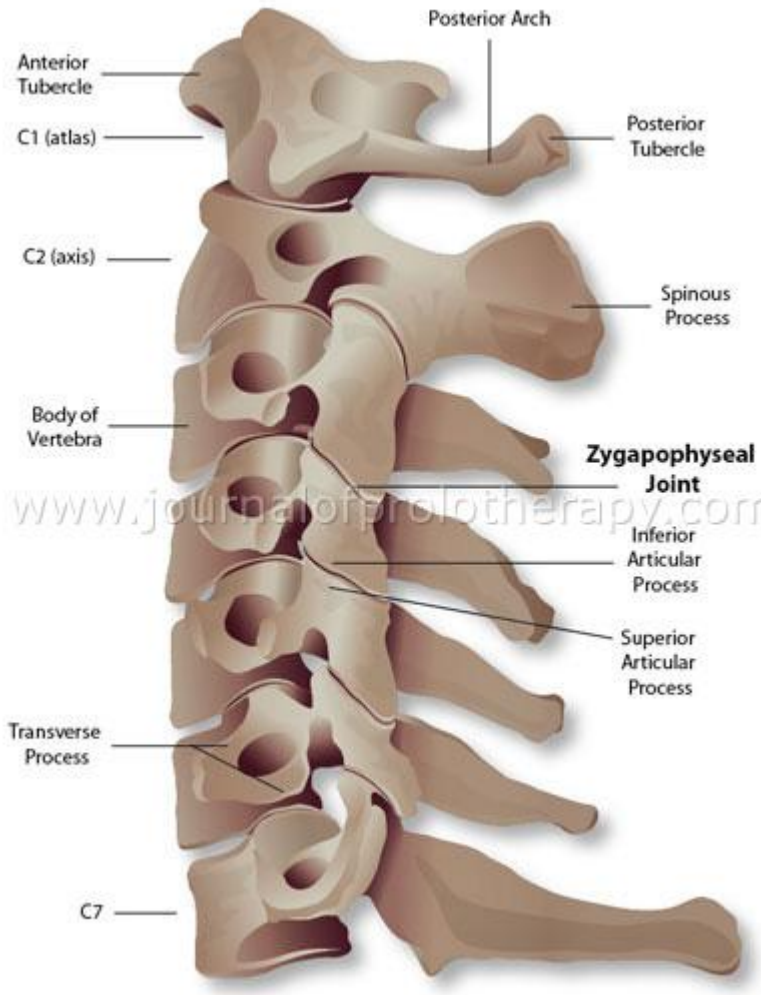
The Vertebral column:

The Vertebral column which lodges and protects the spinal cord, its meninges and the continuation of the central nervous system lies in the dorsum of the body. It forms a pillar which contains 33 segments and lengths about 70 cm in an average male and 60 cm in a female. It supports the body weight and transmits it to the ground through the lower limbs.



THE CERVICAL VERTEBRAE

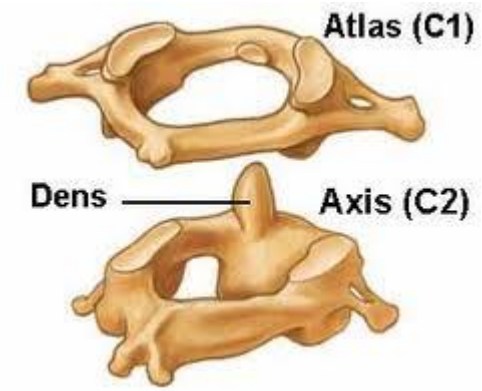
The cervical vertebrae are the smallest of the movable vertebrae. The cervical segment of vertebral column contains 7 vertebrae which include 3 atypical and 4 typical vertebrae.



TYPICAL CERVICAL VERTEBRA

Parts of the typical Cervical Vertebra:

1. Body
2. Vertebral Foramen
3. Vertebral Arch
    - i. Pedicles
    - ii. Laminae
    - iii. Articular facets
    - iv. Transverse processes
    - v. Spinous process
    - vi. Foramen Transversarium



THE ATYPICAL CERVICAL VERTEBRAE:

The following three are the atypical cervical vertebrae:

1. Atlas (first cervical vertebra)
2. The Axis (second)
3. The seventh cervical vertebrae

JOINTS OF THE VERTEBRAL COLUMN

The vertebrae from the 2nd cervical to 1st sacral are articulated to one another by a series of cartilaginous joints between vertebral bodies and a series of synovial joints between the vertebral arches. The vertebral bodies are united by anterior posterior longitudinal ligaments and by intervertebral disc of fibrocartilage.

JOINTS OF THE CERVICAL SPINE

1. Atlanto-occipital Joint:

Flexion, extension and slight lateral flexion are possible movements of this joint.

2. Atlanto-axial Joints:

Consists of a pair of lateral atlanto-axial joints and median atlanto-axial joint.
Movement - Rotatory movements around a vertical axis

3. The Uncovertebral (Luschka's) joints:

Luschka's joints are not true synovial joints.

Luschka's joints are important, because

- They are the commonest sites of osteophyte formation. The osteophytes may compress the cervical nerves.
- Vertebral artery lies lateral to the joints intruding on the canal and can cause distortion of the artery and leads to Vertebro basilar insufficiency in atherosclerotic vessels.

- **Typical Cervical Vertebrae:**

1. Body:

It is small and oval. It's superior surface is concave transversely with upward projecting lips on each side and its inferior surface is saddle shaped, convex from side to side and concave from before backwards.

2. Vertebral Foramen:

It is larger than the body and triangular in shape.

3. Vertebral Arch:

i) Pedicles:

These are short and directed outwards and backwards from the middle of postero lateral parts of the body and they form the postero medial wall of the foramen transversarium.

ii) Laminae:

These are long and narrow, being thinner above than below.

iii) Articular Facets:

The superior and inferior articular processes form the articular pillars which project laterally at the junction of the pedicle and the lamina. The superior articular facets are flat and directed backwards and upwards. The inferior articular facets are also flat but directed forwards and downwards.

iv) The Spine:

It is short and bifid.

Foramen Transversarium:

It transmits the vertebral artery, vertebral veins and sympathetic plexus.

The Atypical Cervical Vertebrae:

1. Atlas:

It is the first cervical vertebrae which lodges the skull. It has no body and spine. It has anterior and posterior arch, right and left lateral masses and transverse processes.

The anterior arch bears an anterior tubercle in the anterior aspect. Its posterior aspect bears an oval facet which articulates with dens. The posterior surface of the posterior arch has a median posterior tubercle. The two lateral masses bear an elongated superior articular facet for atlanto-occipital joint and an inferior articular facet for atlanto axial joint.

2. The Axis:

The Axis has a peg like projection in its upper part of the body known as the dens (or) odontoid process. It has circular facet anteriorly articulating with atlas. There are two articular facets on either side of the dens on the upper surface of the body. The laminae are thick. The spine is large and bifid. The transverse process is small and possesses a tubercle in its tip.

3. The Seventh Cervical Vertebrae:

It is also known as the "Vertebral Prominent". The transverse process does not posses anterior tubercle. The foramen transversarium is small (or) absent. It transmits accessory vertebral vein only. The spine is long.

Movements of the Vertebral Column:

The greater thickness of the discs in the cervical and lumbar regions as compared with the thoracic region is associated with the greater individual range of movements occurring in those regions.

Flexion (or) forward bending, extension (or) backward bending, lateral flexion and rotation are possible in vertebral column.

NORMAL X-RAY

MOVEMENTS:

MOVEMENTS	MUSCLES	NERVE SUPPLY
Flexion	Sternocleidomastoid	Accessory ventral rami of cervical spinal nerves C2, C3, C4
	Longus Coli	Cervical Ventral rami C2 – C6
	Longus Capitis	Cervical Ventral rami C1 – C3
	Rectus Capitis Anterior	C1 Ventral ramus
	Splenius Cervicis and Capitis, Erector Spinae	Dorsal cervical nerve
Extension	Rectus capitis posterior major and minor	Dorsal rami C1
	Obliques capitis superior	C1 – Dorsal ramus
	Trapezius	Accessory
	Sternocleido mastoid	Accessory, Ventral rami of Cervical spinal nerves C2 , C3, C4
Lateral flexion and rotation	Scalene	Cervical Ventral rami C3 – C8
	Longus Coli	Cervical Ventral rami C3 – C8
	Levator Scapulae	Cervical Ventral rami C3 C4, C5
	Rectus Capitis	C1 – Ventral ramus
	Splenius	Cervical dorsal ramus
	Longismus obliques capitis superior and inferior	C1 Dorsal ramus

NERVE AND ROOT SUPPLY OF MUSCLES

UPPER LIMB	SPINAL ROOT
SPINAL ACCESSORY NERVE	
Trapezius	C_3C_4
BRACHIAL PLEXUS	
Rhomboides	C_4C_5
Serratus anterior	$C_5C_6C_7$
Pectoralis Major	
Clavicular	C_5C_6
Sternal	$C_6C_7C_8$
Supra Spinatus	C_5C_6
Infra Spinatus	C_5C_6
Latissimus Dorsi	$C_6C_7C_8$
Teres Major	$C_5C_6C_7$
Axillary Nerve	
Deltoid	C_5C_6
Musculo Cutaneous Nerves	
Biceps	C_5C_6
Brachialis	C_5C_6
Radial Nerve	
Triceps	
Lateral Head	$C_6C_7C_8$
Medial Head	
Brachio radialis	C_5C_6

Extensor Carpi radialis longus	C_5C_6

Posterior Interosseous Nerve

Supinator	C_6C_7
Extensor Carpi Ulnaris	C_7C_8
Externsor digitorum	C_7C_8
Abductor pollicis Longus	C_7C_8
Extensor pollicis Longus	C_7C_8
Extensor pollicis brevis	C_7C_8
Extensor indicis	C_7C_8

Median Nerve

Pronator teres	C_6C_7
Flexor Carpi radialis	C_6C_7
Flexor digitorum superficialis	$C_7C_8T_1$
Abductor pollicis brevis	C_8T_1
Flexor pollicis brevis	C_8T_1
Opponens pollicis	C_8T_1
Lumbricals I & II	C_8T_1

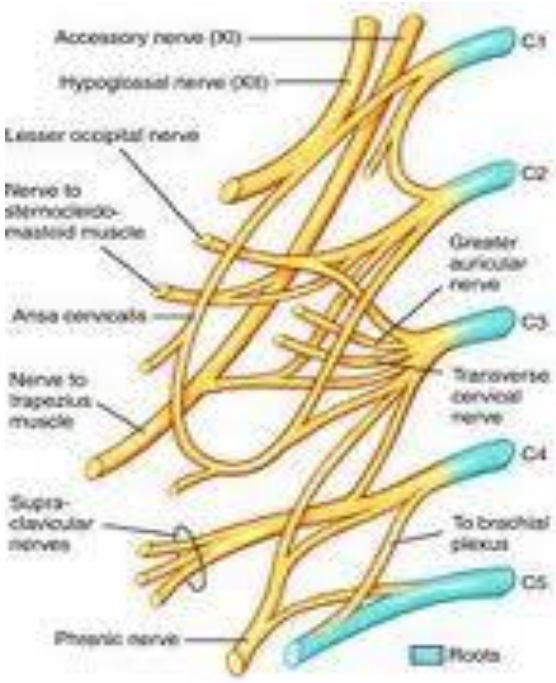
Anterior Interosseous Nerve

Flexor digitorum profundus I & II	C_7C_8
Flexor pollicis longus	C_7C_8

Ulnar Nerve

Flexor carpi ulnaris	$C_7C_8T_1$
Flexor digitorum profounds III & IV	C_7C_8
Hypothenar muscle	C_8T_1

Abductor pollicis	C_8T_1
Flexor pollicis brevis	C_8T_1
Palmar interossei	C_8T_1
Dorsal interossei	C_8T_1
Lumbricals III &IV	C_8T_1



CERVICAL SPONDYLOSIS

- **Nomenclature**
- Cervic(o) - Latin Word, Means neck.
- Spondylo - Greek Word, Means Vertebra
- Osi - Condition

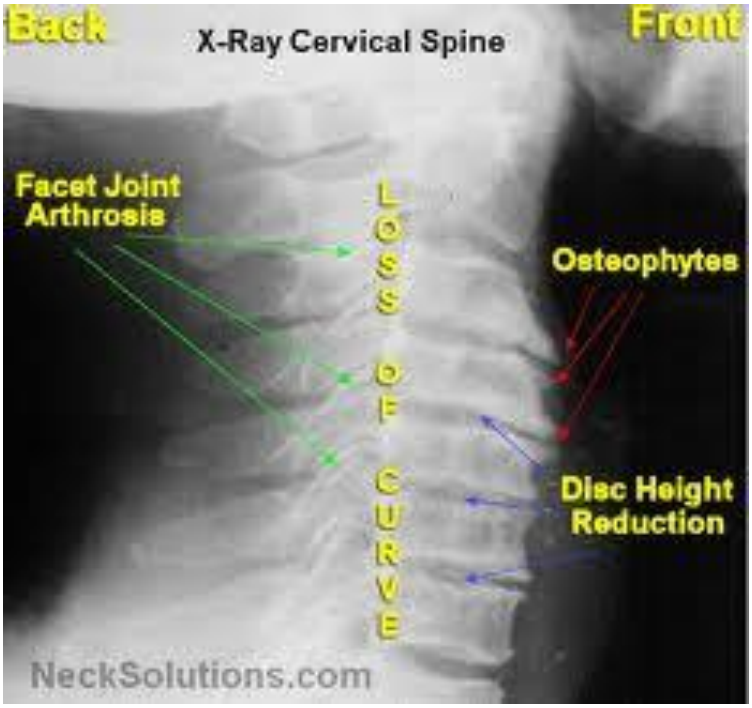
Is a type of pathological condition in cervical vertebra.

DEFINITION:

- Cervical spondylosis is defined as arthrosis of posterior intervertebral joints in the cervical vertebrae , caused by degeneration of intervertebral discs which fragment and collapse with normal ageing with subsequent changes in the bones and soft tissues.

Location:

- Generally the C5 & C6 roots are most commonly affected by cervical Spondylosis as a result of the increased mobility at the C5-C6 & C6-C7 levels.
- Acute disc lesions are seen most often at the C7 level followed by C6
- High level cervical disc involvement are very uncommon
- T1 Radiculopathy is caused by the result of involvement by Pancoast tumor in the apical pleura.



AETIOLOGY

I. Degenerative Causes

They are primary and secondary

- Primary - Senility, genetic factors, metabolic factors and manual labour
- Secondary- Osteoarthritis, rheumatoid arthritis, metastatic carcinoma or lymphomas of the spine and TB spine.

II. Injury

- Automobile accidents with "Whiplash" injury, athletic injury
- Sudden jerks on the arms during fall down
- Previous injury with fracture or disc prolapse

III. Occupational causes

The physical discomfort, which arises through an occupation is occupational stress. The physical strain, intensity of work and duration of working hours all constitutes the occupational strain.

IV. Hereditary factors

Congenital narrowing of the cervical spinal canal (myelopathy is often seen when canal's sagital diameter is 12mm or less). Segmental defects – Hemi vertebra, fused vertebra.

V. Acquired narrowing of cervical spinal canal due to Osteophytes

This occurs due to the following reasons like,

Ossified Posterior Longitudinal Ligament (OPLL).

Facet joint hypertrophy (results in foraminal stenosis and compression of root of radicular artery).

Hypertrophied Ligamentum Flavum (Compress the cord during extension).

Outgrowths of bone sometimes occur with aging. Intervertebral disc protrusions are commonest in the Cervical region which is due to degeneration of the inter vertebral disc. If this involves several discs with osteoarthrosis , this is liable to interfere with blood supply of the cord leading to further damage.

PATHOLOGY:

- Cervical spondylosis is very common and histological evidence of degenerative changes is present in virtually even present over the age of 70. Osteophytes may form posteriorly with osteoarthritis of the apophyseal joints and also anteriorly in relation to degenerative changes and narrowing of the intervertebral disc with sclerosis of the bony end plates. The osteophytes may cause symptoms by encroaching on the spinal nerve foramina or in the cervical region on the vertebral artery foramen. In the cervical region intermittent pain and discomfort may be followed eventually by stiffness and limitation of movements.

- At first injury to chondrocytes occur and therefore, the maintenance of articular cartilage imparirs and if this continues loss or decreased synthesis of proteoglycans occurs. Another theory is with decades of weight bearing,there is remodeling of the articular cartilage with redistribution of load stress chondrocyte intergrity mainly depends on normal level of loads. Chondrocyte degeneration or injury occurs as a result of overloading or under loading and loss of proteoglycans has been contributed by alteration of subsynovial weave of collagen fibres.

Chondrocyte injury causes release of degradative enzymes particularly proteoglycanase and cathepsins. At the same time the capacity of synthesis of proteoglycans diminished due to age and chondrocyte injury. Injury causes alteration in collagens and there occurs change from type II to type I. The Type I collagen withstands minimally to stress. All this causes cartilage injury.

Morphology:

The early changes appear to be erosion and flaking of cartilaginous surface with advance of the disease clefts appear within the cartilage at right angles to the surface. The clefts may penetrate to sub chondral bone producing cartilage fibrillation. Sometimes fragments of cartilage break off to create joint mice. This cartilage injury results in growth of blood vessels from the subchondral bone into articular cartilage. These occur focal cystic areas within the subchondral bone and they contain fibrous tissues. The further progression of the disease, leads to deep or complete erosion of cartilage layer.

The disappeared and leaves denuded subchondral bone which is dense smooth, glistening to ivory. This is known as Eburnation. The loss of cartilage accounts for the so called thinning of joint space, which is seen radiographically.

Osteophytes developing from margins of articular cartilage may sometime extend to the ligamentous and capsular attachment and is called "bone spurs" of osteoarthritis. When large spurs project from opposing bones come into contact causing pain and limitations to movements. These bony spurs accounts for nodules known as "Heberden's nodes."

Intervertebral disc prolapse

This is common cause of compression of the nerve roots and more rarely causes compression of the cord. The inter vertebral disc consists of a central module semifluid matrix, the nucleus pulposus, surrounded by a ring of fibrous tissue and fibrocartilage, the annulus fibrosus. The posterior segment of the annulus is thinner and less firmly attatched to bone and following unusual stress part of the martix of the nucleus pulposus may hereniate through it. The lesion often termed "Slipped disc" may occur after injury and symptoms depend on the direction taken by the extruded matrix. It usually tracks posterior laterally around the expansion of the posterior longitudinal ligament, appearing at one side and compressing the spinal nerve in the intervertebral foramen. Disc protrusion occurs, principally in C5 –C6 and C6 – C7 discs.

A single mid line posterior disc protrusion may compress the spinal cord, obstructing the anterior spinal artery, and is a rare but important cause of permanent damage to the spinal cord if surgical treatment is delayed.

When there are several protrusions, the resulting compression may impair the circulation and variable effects of ischaemia of the spinal cord may result. There may be cavitation of the cord and loss of nerve cells in the severely affected areas, the condition being known as “Spondylotic myelopathy”. Nerve root compression is common than myelopathy.

Common signs and symptoms:

1.Pain in the neck, radiating to the shoulder blades, top of the shoulders, upper arms and hands or back of the head.

2. Crunching sounds with movement of the neck or shoulder muscles.

3.Numbness and tingling sensation in the arms, hands and fingers, some loss of feeling in the hands and impairment of reflexes,

4.Muscle weakness and deterioration.

5.Neck stiffness.

6.Head ache.

7.Dizziness and unsteady gait.

8.With advanced stages, loss of bladder control and leg weakness.

Neural compression syndrome:

Most of the patients suffer from either radiculopathy (or) myelopathy. They may be acute, sub acute or chronic.

SUMMARY OF THE SITE OF LESION

Cervical spondylosis can produce cord compression (upper motor neuron signs) or root compressions (lower motor neuron signs)

C5	Motor	Raised elbows (axillary n.)
	Reflex	Biceps (musculocutaneous n.)
	Sensory	Upper, Lateral arm, near/over deltoid (axillary n.)
	Pain	Upper, Lateral arm, never below elbow
C6	Motor	Elbow supination (radial n.) / pronation (median n.)
	Reflex	Brachioradialis (radial n.)
	Sensory	Lateral forearm (musculocutaneous n.)
	Pain	Lateral forearm, possibly to thumb
C7	Motor	Elbow extension (radial n.)
	Reflex	Triceps (radial n.)
	Sensory	Over triceps, mid -forearm and middle finger
	Pain	Deep pain in triceps, front and back of forearm and to middle finger
C8	Motor	Thumb index pinch (ant interosseus n. off median n. at the elbow)
	Sensory	Medial forearm (antebrachial cutaneous n.)
	Pain	Medial forearm, into the 2 medial fingers
T1	Motor	Finger abduction (ulnar n)
	Sensory	Medial arm (brachial cutaneous n)
	Pain	Deep pain in axilla and shoulder / pain radiating to arm.

Investigation:

1. Plain X- ray of cervical spine, including A.P.. Lateral and oblique views show

- Disc space narrowing
- Osteophyte formation
- Degeneration in facet and uncovertebral joints
- Foraminal stenosis (Seen on oblique films)
- Central stenosis

2. Mylogram – May show compression of the spinal cord

3. C.T Scan (computerized Tomography)

- Confirms degenerative changes
- May demonstrate posterior osteophytes and disc herniation

4. MRI (Magnetic Resonance Imaging)

- Neural compression
- Intrinsic cord changes
- Disc degeneration

5. Examination of CSF:

very high protein

6. Other tests:

Nerve conduction studies.

DIFFERENTIAL DIAGNOSIS

1. Cervical rib
2. Periarthritis shoulder
3. Syringomyelia
4. Spinal cord tumors
5. Carcinomatous infiltration or radiotheraphy
6. Peripheral nerve lesions (distal ulnar or median nerve)
7. Motor neuron disease

COMPLICATIONS

1. Cord compression-Quadriplegia, spastic gait, affecting the bladder.
2. Nerve root compression – Neurological injury, Brachialgia
3. VBI (Vertebro basilar insufficiency)

.**Management:**

1. Non – Operative:

1. Analgesics
2. Local modalities
3. Exercise programme and cervical traction.

2. Operative:

Operative treatment should be considered.

1. In the presence of intractable pain.
2. where there is evidence of radiculopathy or myelopathy.
3. Where osteophytes are producing vertebro basilar insufficiency.

Physiotheraphy:

In acute exacerbation of disease affecting the cervical spine, rest may be the initial treatment.

Cervical Collar:

Cervical collar is advised to wear as temporary collar (Which is often made from Plastazote) for day time to restrict movement, and a soft collar for support at night. A patient who is given a collar should be advised that the restriction in neck movement will alter other proprioception, for example he will need to take care in the dark or on entering darkened rooms when he may lose his balance. A patient wearing a collar should not drive because judgement of relative distances will be impaired. In the cases of vertebro basilar insufficiency (VBI) cervical collar may be advised to the sufferers according to the severity.

Cervical Traction:

Vertebral traction should be the first choice of pain relief for patients suffering nerve root pain. Intermittent sustained traction is carried out after careful positioning of the

involved segmenthas been localized. In such cases the treatment atleast once a day is essential, prolonged pain relief will take several days to obtain.

Cervical traction provides positive patient response and can relieve the pain associated with certain neck disorders. It applies a stretch to muscles, ligaments and tissue components of the cervical spine. It provides relief by promoting separation of the intervertebral joint space, which contains the disc and may reduce a "bulge" or impingement of structures within the foramen. It is no indicated for use in condition of instability such as with "whiplash" injury. It is most commonly used when the patient is in the supine position (lying on the back with knees bent at a 45° angle) with the neck placed at 20° - 30° of flexion (forward tilt). Using traction in this position helps stretch the posterior neck muscles and facilitate intervertebral separation, which relieves pressure that may be pinching nerves, therefore, promoting muscle relaxation and intervertebral separation.

Exercise for Cervical Spondylosis:

To start with, exercises should be done sitting and the feet must rest on the floor or stool. Exercises should be done in front of a mirror, in order to get correct movements.

1. Static Head & Neck Exercise: (no movement take place, muscles are strengthened)

- ★ Place your hand on your forehead, with the hand stop forehead from bending forwards – 3 times increase to 5.
- ★ Place the hand behind the head, with yours hand stop the head from bending backwards - 3 times increases to 5.
- ★ Place right hand on right cheek and ear, stop the head from bending on right side – 3 times increases to 5.
- ★ Place the left hand on left cheek and left ear, stop the head from bending on left side – 3 times increase to 5.
- ★ Place right hand on right lower jaw stop the head from turning to right side -3 times increase 5.
- ★ Place left hand on left lower jaw, stop the head from turning to the left side 3 times increase to 5.

In order words give resistance with your hands to work the muscles as much as possible. Continue the above static exercises. If these suit, otherwise discontinue the static exercises.

2. Excercise for Shoulder:

★ Arms lift forwards, up and down – 5 times increase to 7-10 times

★ Arms lift sideways, up and down – 5 times, increase to 7 -10 times

★ Arms lift forwards, part and together – 5 times increase to 7 -10 times

★ Fingers on the shoulder with elbows bent:

- Elbows circling forwards, upwards, backwards & downwards – 5 times increased to 7 – 10 times
- Elbows circling backwards, upwards, forwards & downwards – 5 times increase 7 -10 times

★ Right hand meeting left hand at the back (Right hand to be carried above the right shoulder, left hand carried from left side at the back and try to touch the right hand) Repeat the left hand carried above the left shoulder and the right hand turned in, carried from the side of trunk -3 times each side, increase to 5 -7 times.

PATIENT EDUCATION:

1. Do not getting look down to read (or do any other work). Bring the reading materials to the eye level.
2. All neck movements can be performed with practice, by using trunk movements.
3. Use a low level pillow supporting the head and neck; pillow line upto the shoulders level. Otherwise not to be encouraged.

Prevention:

1. Avoid sitting in cramped position.
2. Sleep without pillows
3. Use a soft fabric collar or towel to support the neck.
4. Wear protective headgear for contact sports
5. Use seat belts in vehicles .

Prognosis:

The assessment of prognosis is attained by studying the pathological condition of the spinal cord and nerve roots. Improvement can be felt with some of the reversible changes with drug treatment. In complicated cases improvement is not possible. The signs and symptoms due to myelopathy are unmanageable. Long history of suffering multiple disc lesions and in severe compression of spinal cord may adversely affect the prognosis.

PROPERTIES OF TRIAL DRUG

எருக்கு

: 

வேறு பெயர்:அருக்கன்

Botanical name: Calotrophis gigantean.Linn

Family:asclepediaceae

Eng.name:madar

Action:

Anthelmentic

Alternative

Laxative

Stimulant

Organoleptic characters:

Taste : Bitter, pungent

Potency : Hot

Pirivu : pungent

குணம்

எலிவிடம் குட்டமைய மேறு கிருமி

வலிசூலை வாயுவிட மந்தம்-மலபந்தம்

எல்லா மகலு மெருக்கிலையைக்கண்டால்

வில்லார் நுதலே விளம்பு.-

குணபாடம் மூலிகை

Phytochemicals:

Calotropin,leucocyanidin,calophyllolide posses anti -inflammatory action.The ethanolic extract of calotropis gigantea(leaf) possess anti-inflammatory activity against carragenan induced paw oedoma.

In ayurveda the leaves of C. gigantea are used in the treatment of paralysis, swellings and intermittent fevers. Leaves of C. gigantea were reported to carry antioxidant activity.

கறியுப்பு

English name:sodium chloride

குணம்

அளத்திலுறை நல்லுப் பனல் வாதம் மாற்றுங்
களத்துநோய் தன்னைக் களையும்-கிளைத்தகப
ஆகடைய வல்லைநோய் அஷ்டகுன்மமும் போக்குங்
காசினியுள் மாதே கழறு

குணபாடம் தாது சீவ வகுப்பு

Action:

Laxative

Emetic

Anodyne

Organoleptic characters:

Taste : Salt

Pirivu : Salt

CHEMICAL PROPERTIES

Characters	White, crystalline powder or colorless crystals. Freely soluble in water, cally insoluble in ethanol.
Acidity or Alkalinity	Comply with the standard
Appearance of solution	Clear and colorless
Iodides	No blue color is abserved
Bromides	Comply with the standard
Ferro cyanides	Comply with the standard
Nitrites	≤0.01
Phosphates	≤0.0025%
Sulfates	≤0.02%
Aluminum	≤0.00002%
Barium	Comply with the standard
Potassium	≤0.05%
Iron	≤0.0002%
Magnesiumandalkaline-earth metals Calculated as Ca	≤0.01%
Arsenic	≤0.0001%
Heavy metals(pb)	≤ 5ppm
Loss on drying	≤0.5%
Bacterial end toxins	≤ 5 I.U.
Assay	99.0~100.5%

நல்லெண்ணெய்:

Botanical Name **:** Sesamum indicum,Linn.

Family **:** Pedaliaceae

English name: Sesame,Gingeli oil plant,Gingelly

Sans name: Tilam

Hindi name: Thil

Parts used : Leaf, flower, unripe fruit, seed

Organoleptic characters:

Taste : Sweet.

Potency : Hot

Pirivu : Sweet

Activities:

Oil :

- Demulcent
- Laxative
- Nutritive
- Emollient

Phytochemicals:

- Sesamin
- Sesemol

General characters:

“புத்திநயனக்குளிர்ச்சி பூரிப்பு மெய்ப்புளகஞ்

சத்துவங் கந்தி தனியிளமை - மெத்தவுண்டாங்

கண்ணோய் செவிநோய் கபாலவழல் காசநோய்

புண்ணோய்போ மெண்ணெய்யாற் போகூழ்.”- குணபாடம் மூலிகை

Uses:

Gingelly or sesame oil: oil extracted from seed of Sesamum indicum: It has actions. On external application it heals burns and ulcers. Recently, sesame oil and its lignan sesamol have been proved to be potent anti-inflammatory agents. They have an excellent protective effect against endotoxin-associated inflammatory damage because they inhibit the release of inflammatory mediators. Sesamol also inhibits endotoxins from binding to its receptor; this reduces inflammatory transcription factor NF-κB activation. In summary, sesame oil or sesamol may be beneficial for reducing the inflammatory response in inflammation-associated diseases.

பூனைக் கண் குங்கிலியம்

BOTANICAL NAME:Pistacia lentiscus

FAMILY: Anacardiaceae

ACTION:Stimulant diuretic

COMPONENT: the major component of the drug are α-Pinene, β-myrcene, β-pinene, limonene, and β-caryophyllene . The topical anti-inflammatory activity of essential oil of Pistacia lentiscus L. was studied using carrageenan induced rat paw edema and cotton pellet induced granuloma. It can be concluded that the essential oil of Pistacia lentiscus reduces leukocyte migration to the damaged tissue and exhibits anti-inflammatory activity.

PREPARATION OF THE TRIAL DRUGS

INTERNAL DRUG: KAIUPPU CHENDURAM

Ref:Anuboga Vaithiya Navaneetham part-3

KARIUPPU CHENDURAM

அளத்திலுறை நல்லுப் பனல் வாதம் மாற்றுங்
களத்துநோய் தன்னைக் களையும்-கிளைத்தகப
ஆகடைய வல்லைநோய் அஷ்டகுன்மமும் போக்குங்
காசினியுள் மாதே கழறு

\- குணபாடம் தாது சீவ வகுப்பு

INGREDIENTS:

- Eruku leaf (Calotropis gigantea .*linn*
- Kariuppu (Sodium Chloride)

PURIFICATION OF DRUGS:

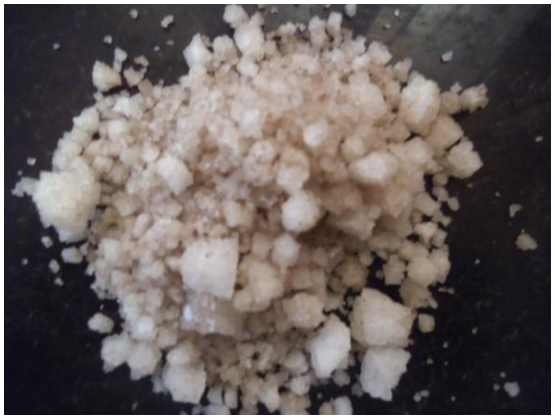
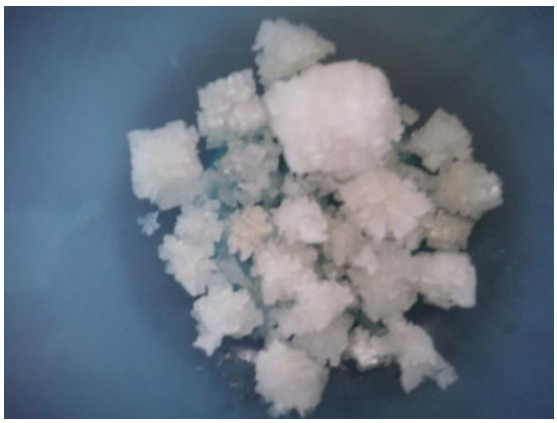
Calotropis gigantea - wipe the leaf with a clean cloth.
Sodium Chloride - first dissolve with butter milk and then dry it in sunlight.

METHOD OF PREPARATION:

Kariuppu (sodium chloride) is kept in a mortar . The paste of tender leaf of Calotropis gigantea is placed in a fine cloth and the juice is squeezed out, the juice is added to kariuppu kept in mortar and grounded for 3 hours . Then the contents are made into cakes and dried. The dried cakes are placed in a mud pot and covered by another mud pot of same size. It is sealed by using 3 layers of mud pasted cotton cloth and dried. The dried mud pot is subjected to pudam by using cowdung cakes weighing 20 times of dried drug containing mud pot. The same process is repeated for 4 more time .

Dose	: 2 kundri alavu (260mg)Twice daily
Adjuvant	: Honey.
Route of drug administration	:oral route
Duration	: 48 days

KARIUPPU

	
BEFORE PURIFICATION	**AFTER PURIFICATION**

KARIUPPU CHENDURAM

KUNTHIRIKA THYLAM

	
POONAIKAN KUNGILIYAM	**SESAME OIL**

KUNTHIRIKA THYLAM

PROTOCOL

TITLE:

THE CLINICAL AND PRE CLINICAL STUDY TO EVALUATE THE THERAPEUTIC EFFICACY OF **KARIUPPU CHENDURAM (INTERNAL)** AND **KUNTHIRIKA THAILAM (EXTERNAL)** IN THE TREATMENT OF "**CEGANA VATHAM**" **(CERVICAL SPONDYLOSIS**).

OBJECTIVE:

Primary objective:

To evaluate the therapeutic efficacy of **KARIUPPU CHENDURAM (INTERNAL)** AND **KUNTHIRIKA THAILAM (EXTERNAL)** in

Cegana Vatham.

Secondary objectives:

To evaluate the safety profile (acute, long term toxicity studies) of the trail drug.

To study the other co factors such as age, sex and siddha parameters.

STUDY DESIGN & CONDUCT OF STUDY:

STUDY TYPE **:** An open clinical trial

STUDY PLACE **:** OPD. & IPD. Of Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram sanatorium, Chennai-47.

STUDY PERIOD **:** 12 months

SAMPLE SIZE **:** 40 patients

TREATMENT:

NAME OF THE MEDICINE:

KARIUPPU CHENDURAM (Internal)

Reference **:Anupoga vaithya navaneetham part-3**

Author hacki pa.mu.Abdullah saayabu

Pg.no 36,37,2nd Edition:2001

Dose : 2 kundri alavu (**260mg**)Twice daily after food

Adjuvant : Honey.

Route of drug administration:oral route

Duration : 48 days

Diet restriction **:** To avoid root tubers, tamarind, tea , coffee, smoking and alcohol.

KUNTHIRIKA THAILAM (External).

Reference **:** (Pharmacopoeia of hospital of indian medicine Pg.no:133,2nd edition 1995)

Dosage **: Sufficient quantity (50ml)**

SOURCE OF RAW DRUGS:

The required raw drugs are purchased from a well reputed country shop.The raw drugs are athendicated by the head of the department of gunapadam,NIS .The raw drugs are purified and the medicine is prepared in Gunapadam lab of National Institute of Siddha.

STANDARD OPERATING PROCEDURE

KARIUPPU CHENDURAM:

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KUNTHIRIKA THAILAM:

INGREDIENTS:

1) Poonaikan kungiliyam(Pistacia lentiscus) -4 palams.(140 gram)

2) Gingelly oil -40 palams(1400 ml)

PURIFICATION OF DRUGS:

Poonaikan kungiliyam – boil in tender coconut water[7].

METHOD OF PREPARATION:

Mix the ingredients 1 & 2 and boil till kungiliyam dissolves.

INCLUSION CRITERIA:

- Age: 20-50 years.
- Sex: Both sex.
- Neck pain radiating to upper limbs with or without numbness, giddiness and neck stiffness.
- Patient who are willing to withdrawl NSAID.
- Radiological diagnosis of cervical spondylosis.
- Willing to be attented in the hospital or attend the opd once in 12 days for 48 days.

EXCLUSION CRITERIA:

- Cervical rib
- Traumatic conditions
- Rheumatoid arthrities
- Ankylosing spondylosis
- Tuberculosis in spine
- Diabetes mellitus
- Hypertension and cardiac diseases
- Renal disease
- Narcotic addicts
- Pregnancy and lactations

WITHDRAWAL CRITERIA

- Intolerance to the drug and development of serious adverse reactions during drug trial.
- Poor patient compliance and defaulters.
- Patient turned unwilling to continue in the course of clinical trial.
- Occurrence of any serious illness

TESTS AND ASSESMENTS

Clinical assessment

Routine investigations

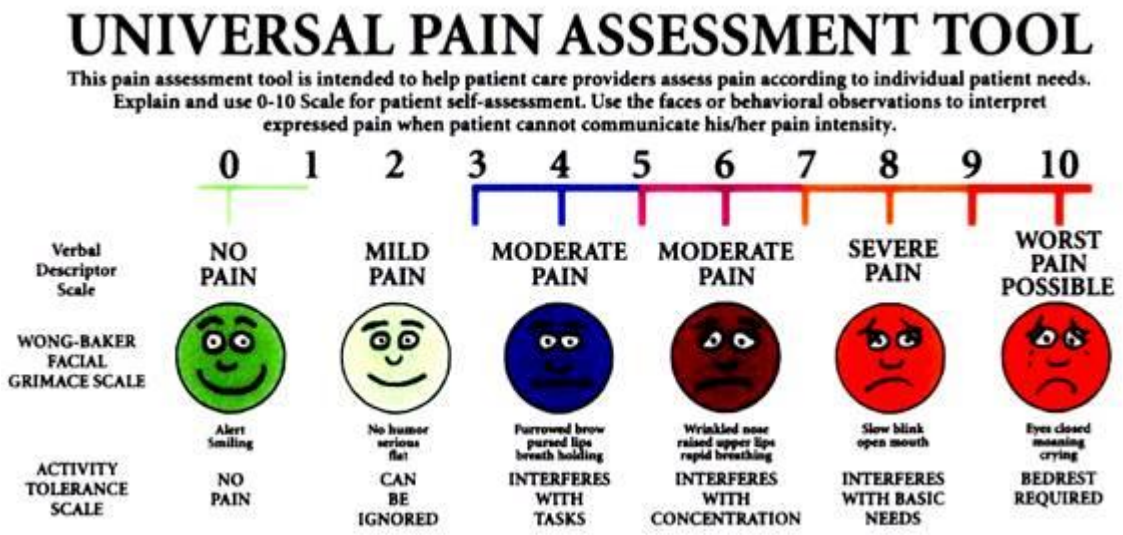
Specific investigations

CLINICAL ASSESSMENT:

- Pain below the neck, above the hip and in both upper limbs.
- Scorpion sting like pain in the above regions.
- Heaviness of the body,
- Burning sensation of the eyes and constipation.

PAIN ASSESMENT:

UNIVERSAL PAIN ASSESMENT SCALE



A. 0 : No Pain

B. 1 -2 : Mild pain

C. 3-4 : Moderate pain(interferes with task)

D. 5-6 : Moderate pain(interfere with concentration)

E.7-8 : severe pain

F.9-10 :Worst pain

SIDDHA ASSESSMENT

1.Thinai :

- Kurinchi (hill areas)
- Mullai (forest)
- Marutham (fertile land)
- Neidhal (coastal area)
- Palai (desert)

2. Paruva Kalam (season)

- Karkaalam
- Koothir kaalm
- Munpanikaalm
- Pinpani kaalam
- Ilavenil kaalam
- Muthuvenil kaalam

3. **Poripulankal:**

- Mei (Skin etc)
- Vaai (Tongue etc)
- Kan (Eye etc)
- Mooku (Nose etc)
- Sevi (Ear etc)

4.Kanmedriyamand Gnanenthiriyam:

- Vaai (Buccal cavity)
- Kaal (Lower limbs)
- Kai (Upper limbs)
- Eruvaai (Anorectal region)
- Karuvaai (Uro-genital region)

5. **Ezhuudalkattugal:**

- Saram

- Senneer
- Uoon
- Kozhuppu
- Enbu
- Moolai
- Sukkilam /suronitham

6.Ennvagaithervu (Eight types of Examination):

- Naadi
- Sparisam
- Naa
- Niram
- Mozhi
- Vizhi
- Malam
- Moothiram

  -Neerkuri

  -Neikuri

SIDDHA PARAMETERS

Malam

Moothiram

B . ROUTINE INVESTIGATION

- HB(gm/dl)
- Total WBC Count(cells/cumm)
- DC- Polymorphs(%)
- Lymphocytes(%)

- Eosinophils (%)
- Monocytes (%)
- Basophils(%)
- Total RBC count million cells/cumm)
- ESR(Men 6-12mm/hr Women 7-18 mm/hr)
- B.glucose (mg/dl)

LIPID PROFILE

- Serum cholesterol(mg/dl)-
- HDL cholesterol(mg/dl)-
- LDL cholesterol(mg/dl)-
- VLDL cholesterol(mg/dl)-
- Serum triglycerides (mg/dl)-

KIDNEY FUNCTION TEST

- B.urea(mg/dl)
- S. total creatinine (mg/dl)

LIVER FUNCTION TEST

- S.total bilirubin(mg/dl)
- S.direct bilirubin (mg/dl)
- S. indirect bilirubin (mg/dl)
- SGOT(u/l)
- SGPT (u/l)
- S.alkaline phosphataseu/l)
- S.total protein(g/dl)
- S. albumin (g/dl)
- S.globulin (g/dl)
- S. calcium (mg/dl)
- S. phosphorous (mg/dl)

URINE EXAMINATION

- Albumin
- Sugar (Fasting & post prandial)
- Deposits
- Bile salts
- Bile pigments
- Urobilinogen

MOTION - Ova

Cyst

SPUTUM - AFB

SPECIFIC INVESTIGATIONS:

X- ray : Cervical spine AP, lateral view.

3. OTHER INVESTGATIONS:

CRP , RA factor.

STUDY ENROLLMENT:

- In this study patients reporting at nis OPD with clinical features of pain in nape radiating to upper limbs, stiffness are chosen for enrollment based on the inclusion criteria.
- The patients who are to be enrolled will be informed (Form IV A) about the study, trial drug, possible outcomes and objectives of the study in the language and terms understandable to them.
- After ascertaining patient's willingness, informed consent will be obtained in written form from them in the consent form (Form IV A).
- All these patients will be given unique registration card with details like Patient's Registration number of study, Address, Phone number and Doctor's Phone number, etc, so as to report easily when any complication arise.
- Complete clinical history, compliance and duration, examination findings will be recorded in the prescribed proforma in the history and clinical forms

separately. Screening Form I will be filled up: Form I-A, Form II and Form III will be used for recording the patient's history, clinical examination and laboratory investigations respectively.

- Patients will be advised to take the trial drug and appropriate dietary advice will be given (Form IV D)

CONDUCT OF THE STUDY:

- Purgation with Agasthiyar kuzhambu – 130 mg early morning with ginger juice will be given for balancing the deranged mukkutram a day before treatment.

- The trial drug **KARIUPPU CHENDURAM (internal) and KUNTHIRIKA THAILAM (external)** are given continuously for 48 days.
- For In-patients, the trial drugs will be given daily. The clinical assessment will be made daily and recorded in the appropriate forms.
- For out-patients, the trial drugs will be given in the Out-patient Department (Room No: 1) of our Hospital. The out-patients will be asked to follow regular check up in the OP Department once in 12 days for 48 days. In each visit, the clinical assessment will be recorded.
- The laboratory and radiological investigations will be done before and after treatment and recorded in the prescribed format.
- At the end of the treatment the patients are advised to have follow up visits in the OPD for 2 more months.
- If any trial patient fails to collect the trial drug on prescribed day, but wants to continue in the trial from next day or two he/she will be allowed.
- Defaulters for one week will not be allowed to continue and will be withdrawn from the study with fresh case being included.

DATA MANAGEMENT:

- After enrolling the patient in the study, a separate file for each patient will be opened and all forms will be filed in the file. Study No. and Patient No. will be entered on the top of file for easy identification. Whenever study patient visits OPD during the study period, the respective patient file will be taken and necessary recordings will be made at the assessment form or other suitable form.
- The screening forms will be filed separately.

- The Data recordings will be monitored for completion and adverse event by HOD and Sr. Research Officer (Statistics) and adverse event by pharmacovigilance dept of NIS.All collected data will be entered into computer using ms access software .Data entry will be 100% cross checked manually. All forms will be further scrutinized in presence of Investigators by Sr. Research Officer (Statistics) for logical errors and incompleteness of data to avoid any bias. No modification in the results is permitted for unbiased reports.

STATISTICAL ANALYSIS:

All collected data will be entered into the computer and manually cross-checked the correctness of the data entry. The clinical symptoms and size of the stone will be analysed by comparing the two point of data(before and after treatment) paired test and chi-square test will be employed to study the efficacy of treatment. Futher, the effect of age and sex will also be analysed.

OUTCOME

PRIMARY OUTCOME

Reduction of neck pain and radiating to the upper limbs is assessed by pain assessment scale.

SECONDARY OUTCOME

1.Reduction in other clinical symptoms.
2.Siddha co-factors

ADVERSE EFFECT/SERIOUS EFFECT MANAGEMENT:

If the trial patient develops any adverse reaction, he/she would be immediately withdrawn from the trial and reffered to the pharmacovigilance dept of NIS.

ETHICAL ISSUES:

1. Informed consent will be obtained from the patient explaining in the understandable language to the patient.
2. After the consent of the patient (through consent form) they will be enrolled in the study.
3. The data collected from the patient will be kept confidentially. The patient will be Informed about the diagnosis, treatment and follow-up.
4. No other external or internal medicines will be used. There will be no infringement on the rights of patient.
5. To prevent any infection, while collecting blood sample from the patient, only disposable syringes, disposable gloves, with proper sterilization of lab equipments will be used.
6. Treatment would be provided free of cost.
7.The patient who are excluded (as per excluded criteria)are given proper treatment with full care at NIS.
8.In conditions of treatment failure , adverse reactions, patients will be given alternative treatment at the National Institute of Siddha with full care throughout the end.

OBSERVATIONS AND RESULTS

Results of the study were observed with respect to the following criteria;

1. Age distribution
2. Gender distribution
3. Diet
4. Religion
5. Gunam
6. Body constituent
7. Seasonal variation
8. Socioeconomic status
9. Occupation
10. Derangement of Vaatham
11. Derangement of Pitham
12. Kanmendrium
13. Gnanenthiriam
14. Derangement of Udal thathukkal
15. Derangement of Envagai thervu

17. Naadi

18. Neikkuri

19.Duration of illness

20.Clinical features

2 .Progress

22.Nature of pain

23.Aggrevating factor on movement

24.Relieving factor on rest

25.Restriction of movement

26.Result

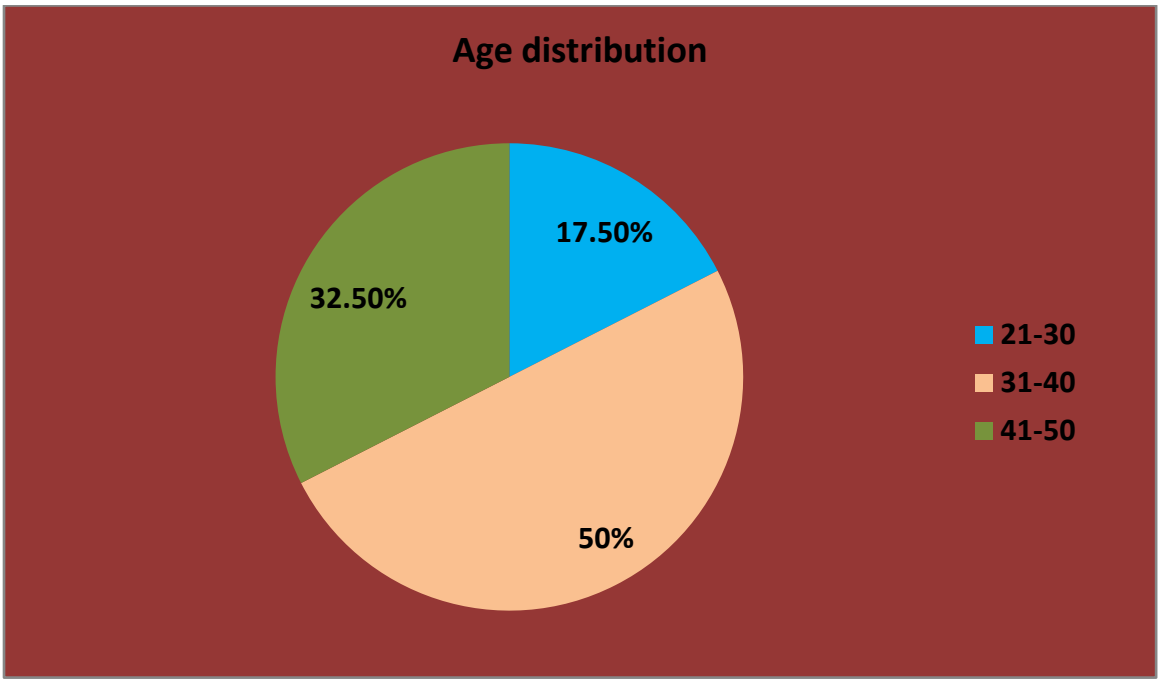
27.Statistical analysis

RESULTS AND OBSERVATION

AGE DISTRIBUTION

TABLE :1

S.No	Age distribution	No. of Cases	Percentage
1	21-30	7	17.5%
2	31-40	20	50%
3	41-50	13	32.5%
	Total	40	100%



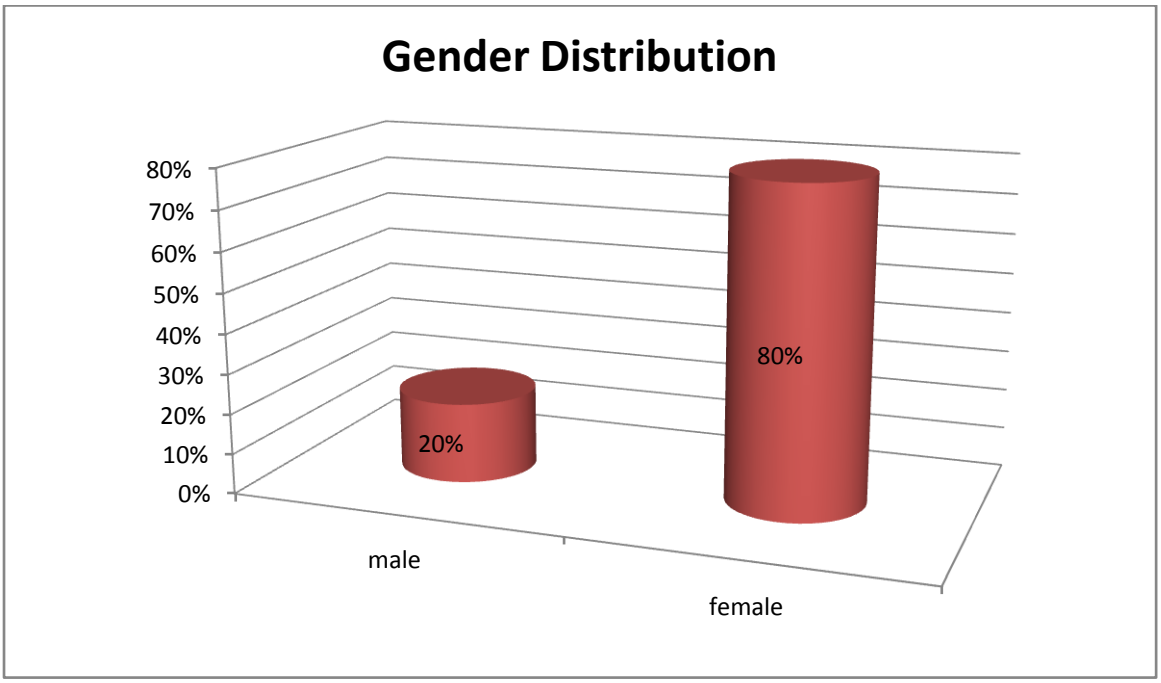
INFERENCE:

Out of the 40 cases taken for clinical trial, 7 (17.5%) cases were in the 21-30 years age group, 20(50%) cases were in the 31-40 years age group and 13 cases (32.5%) were in the 41-50 years age group.

GENDER DISTRIBUTION:

TABLE :2

S.No	Sex	No. of Cases	Percentage
1	Male	8	20%
2	Female	32	80%
	Total	40	100%



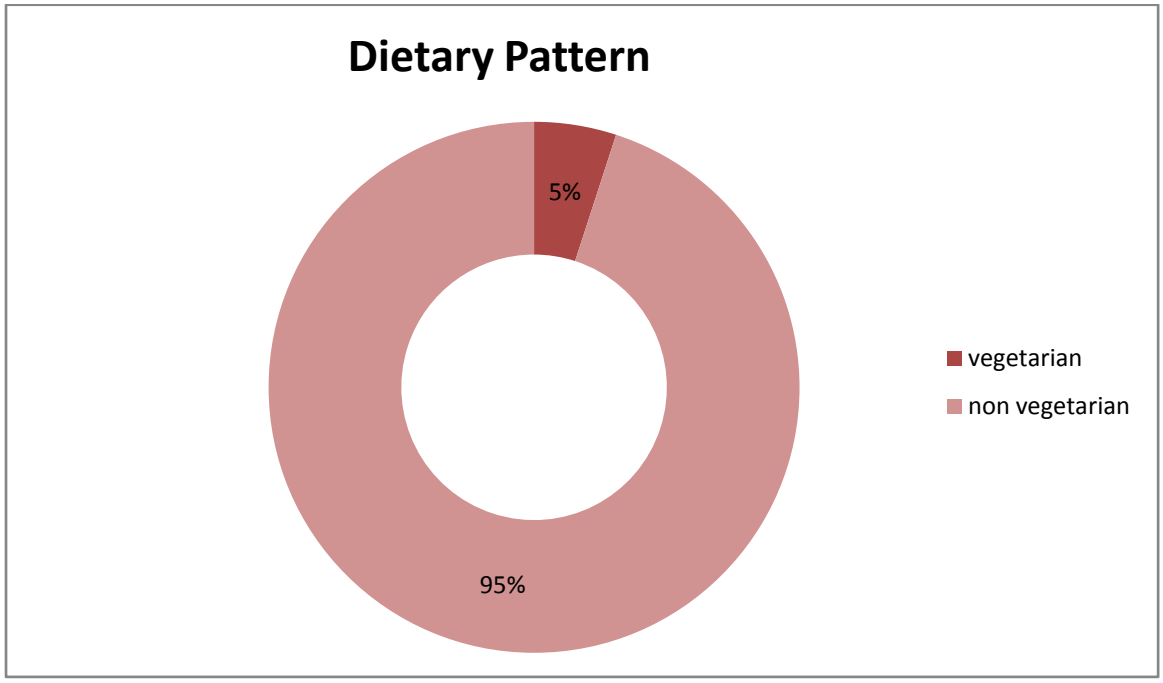
INFERENCE:

In the 40 cases treated, 8 (20%) were male and 32 (80%) were female.

DIETARY PATTERN:

TABLE:3

S.No	Diet Habits	No. of Cases	Percentage
1	Vegetarian	2	5%
2	Non – Vegetarian	38	95%
	Total	40	100%



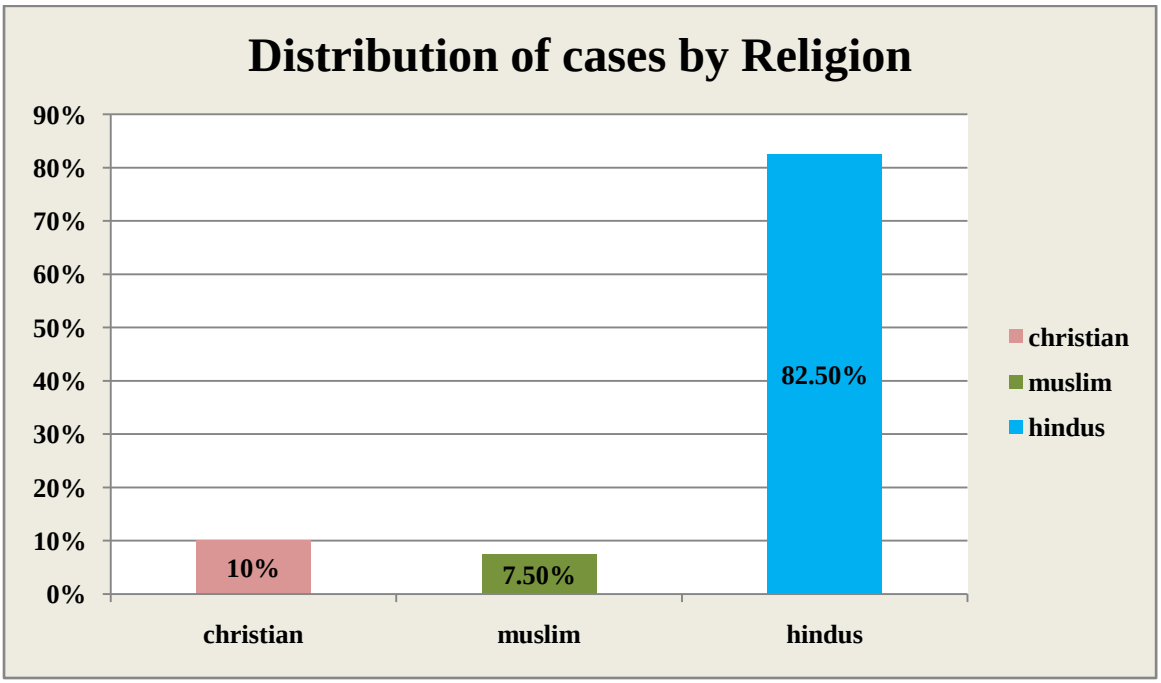
INFERENCE:

Out of the 40 cases, 2(5%) cases were vegetarians and the rest 38(95%) cases had both vegetarian and non-vegetarian foods for diet.

DISTRIBUTION OF CASES BY RELIGION

TABLE:4

S.No	Religion	No. of Cases	Percentage
1	Christian	4	10%
2	Muslim	3	7.5%
3	Hindus	33	82.5%



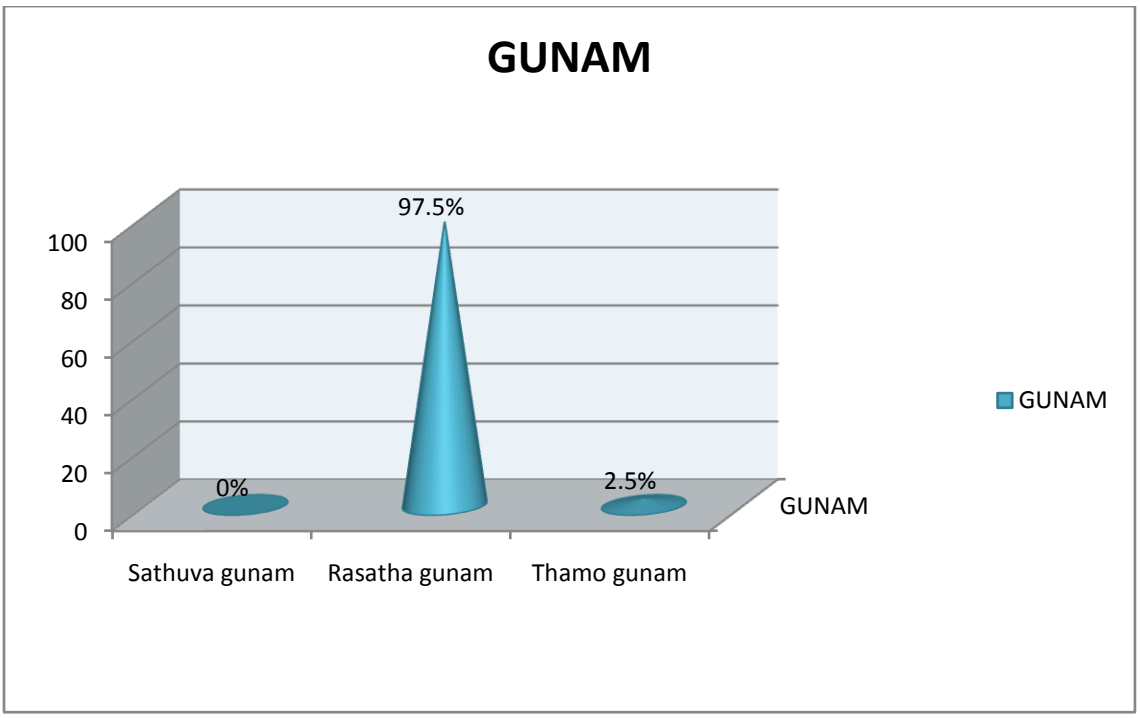
INFERENCE:

Out of the 40 cases taken for clinical trial, 4 (10%) cases were christians, 3(7.5%) cases were muslims and 33(82.5%) were hindus.

DISTRIBUTION OF CASES BY GUNAM

Table: 5

GUNAM	NUMBER OF CASES	PERCENTAGE
Sathuva gunam	0	0%
Rasatha gunam	**39**	**97.5%**
Thamo gunam	1	2.5%
Total	40	100

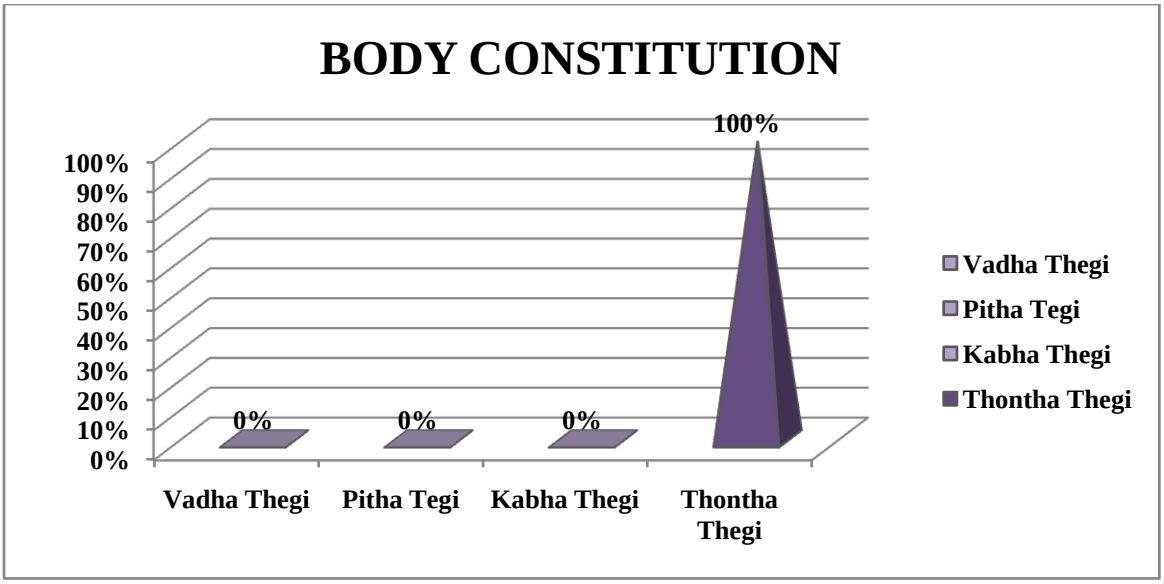


INFERENCE: Among the 40 patients selected, 39 (97.5%) cases were found to possess Rasatha gunam

S. No	ConstitutionOf The Body	No. Of Cases	Percent
1.	Vadha Thegi	0	0%
2.	Pitha Tegi	0	0%
3.	Kabha Thegi	0	0%
4.	Thontha Thegi	40	100%

.

BODY CONSTITUTION : Table 6

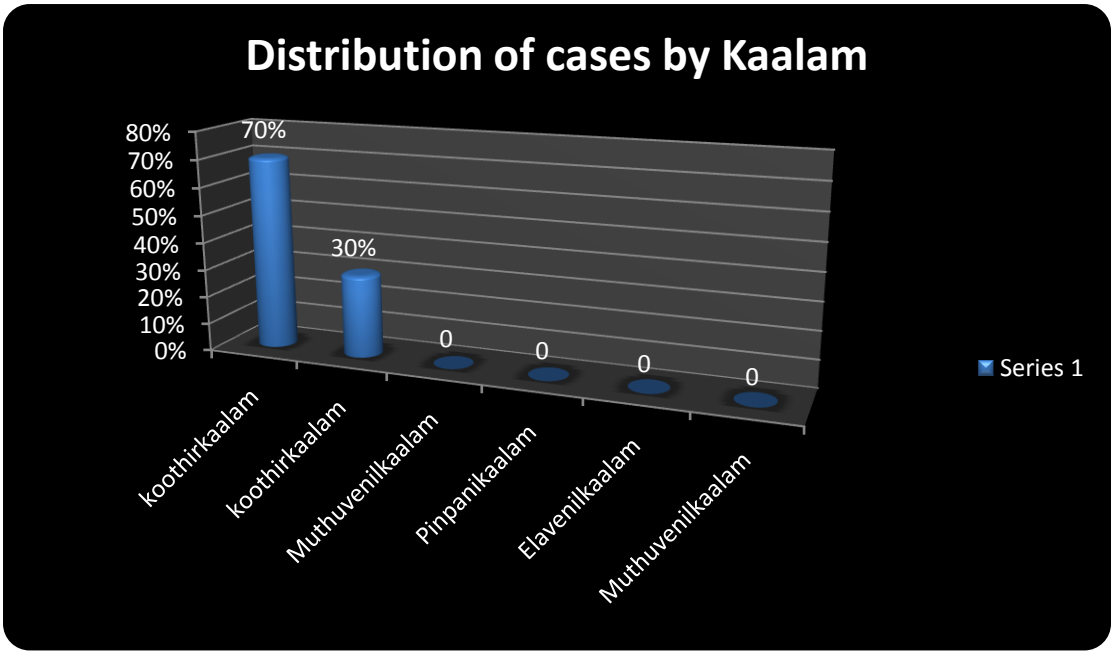


INFERENCE: All the 40 cases (100%) are found to be thontha thegi.

SEASONAL REFERENCE :

TABLE:7

S.No	Season	No. of Cases	Percentage
1	Kaarkaalam	28	70%
2	Koothirkaalam	12	30%
3	Munpanikaalam	-	-
4	Pinpanikalaam	-	
5	Elavenil Kalaam	-	-
6	Mudhuvenil Kaalam	-	-
	Total	40	100%

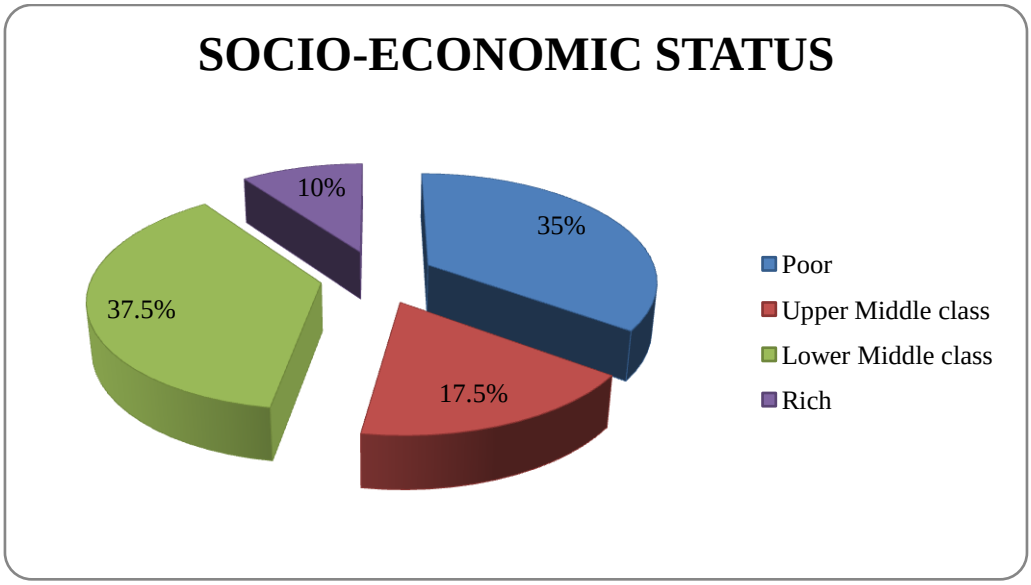


INFERENCE :In the trial of 40 cases, majority of 28(70%) cases were registered in kaar kalam, 12(30%) during koothir kalam .

SOCIO-ECONOMIC STATUS

Table: 8

SOCIO-ECONOMIC STATUS (In terms of Income status)	NUMBER OF CASES	PERCENTAGE
Poor	**14**	**35%**
Upper Middle class	7	17.5%
Lower Middle class	**15**	**37.5 %**
Rich	4	10 %
Total	40	100%

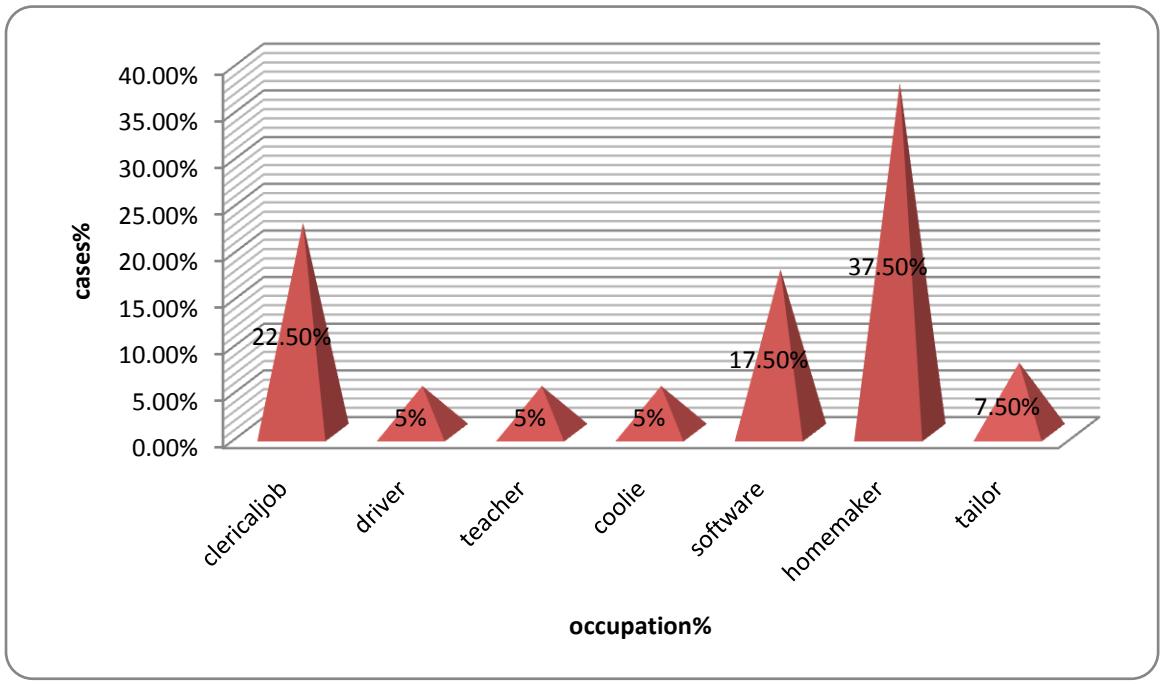


INFERENCE : The incidence of the disease was found to be higher in 15(37.5%) cases belonging to lower middle class and in 14(35%) cases belonging to poor class

OCCUPATION:

TABLE:9

OCCUPATION	PATIENTS	
	NO.	PERCENTAGE
Clerical job	9	**22.5%**
Driver	2	5%
Teacher	2	5%
Coolie	2	5%
Software professional	7	**17.5%**
Home maker	15	**37.5%**
Tailor	3	7.5%
Total	40	100%



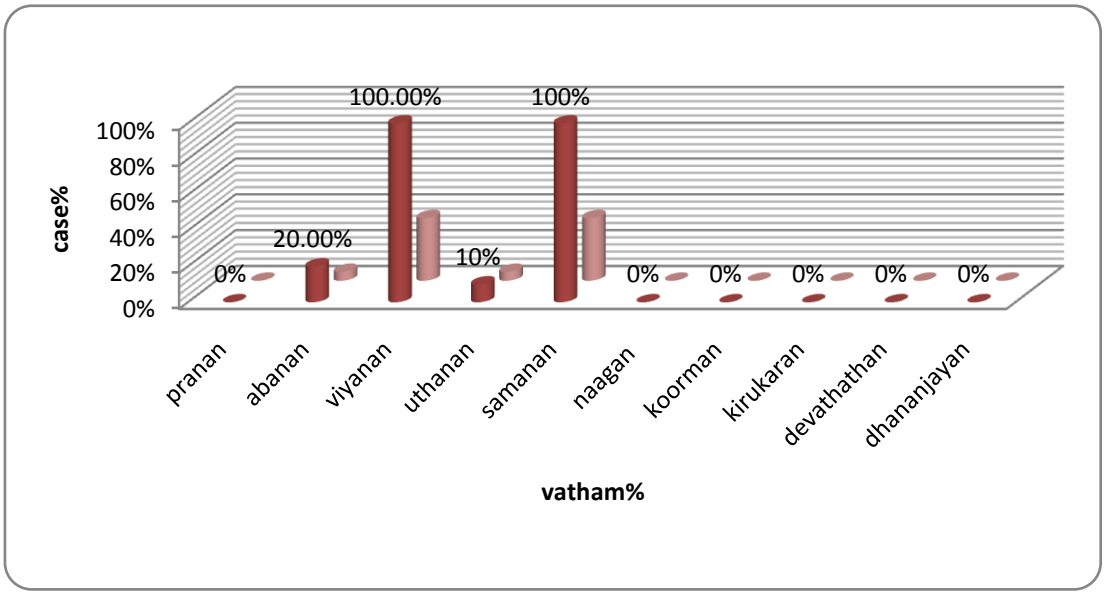
INFERENCE :Among 40 patients recruited for the clinical study 9 patients were from clerical job,each two cases were driver, teacher and coolie.3 cases were tailor 7 cases were softwere proffesionels and 15 patients were home maker.

DISTURBANCES IN VATHAM:

TABLE:10

VATHAM	PATIENTS		PATIENTS		PATIENTS
	BEFORE TREATMENT	%	AFTER TREATMENT	%	RELIEVED FROM
Pranan	0	-	0	-	-
Abanan (constipation)	8	20%	2	5%	15%
Uthanan (cough)	4	10%	2	5%	5%
Viyanan	40	100%	14	35%	65%
Samanan	40	100%	14	35%	65%
Naagan	0	0%	0	0%	-

Koorman	0	0%	0	0%	-
Kirukaran	0	0%	0	0%	-
Devathathan	0	0%	0	0%	-
Dhananjayan	0	0%	0	0%	-



Inference:

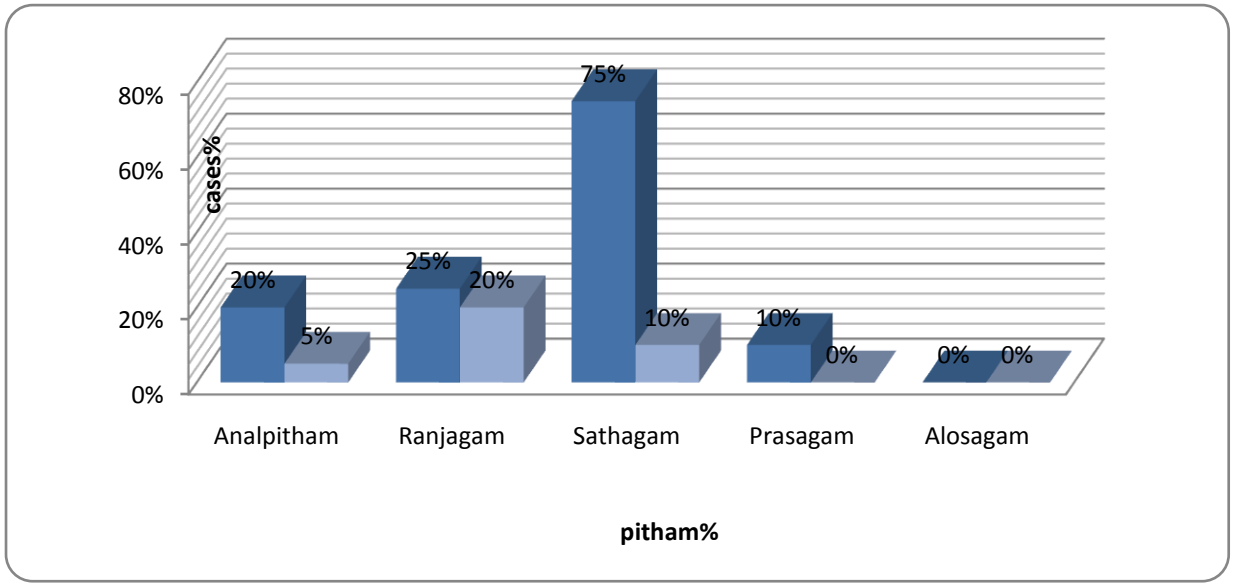
Among the 40 patients observed Viyanan (pain in neck) and Samanan (due to viyanan affected) were affected in almost all the cases, while Abanan (constipation) was affected in 8 cases, Uthanan in 4 cases, before treatment. After treatment Viyanan and Samanan remained affected in 14 cases,abanan and uthanan in 2 cases.

DISTURBANCES IN PITHAM:

TABLE: 11

PITHAM		PATIENTS AFFECTED			PATIENTS RELIEVED FROM SYMPTOMS
	BEFORE TREATMENT	**%**	**AFTER TREATMENT**	**%**	

Analpitham	8	20%	2	5%	15%
Ranjagam	10	25%	8	20%	5%
Sathagam	30	75%	4	10%	25%
Prasagam	4	10%	0	0%	10%
Alosagam	0	0%	0	0%	0%

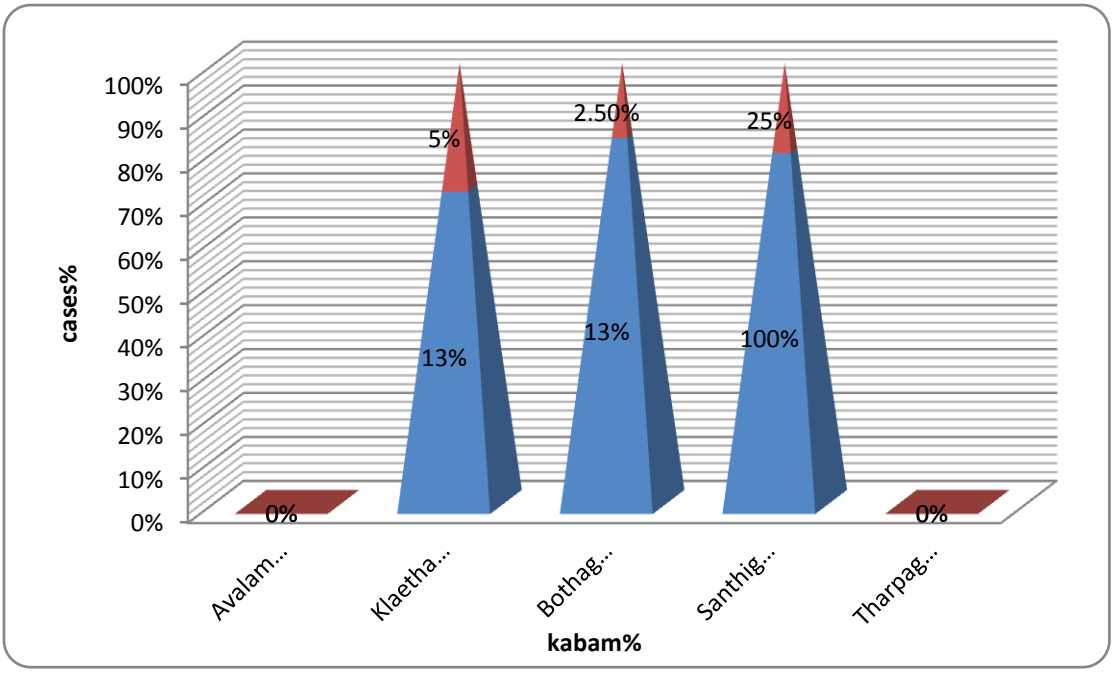


Inference: Among 40 patients sathagam (pain is present nape of the neck) is affected in 75%.ranjakam is affected in 25% of cases.prasagam is affected in 10%cases.

DISTURBANCES IN KABAM:

TABLE :12

KABAM		PATIENTS AFFECTED			PATIENTS RELIEVED FROM SYMPTOMS
	BEFORE TREATMENT	%	AFTER TREATMENT	%	
Avalambagam	0	0%	0	0%	0%
Klaethagam	5	12,5%	2	5%	7.5%
Bothagam	5	12.5%	1	2.5%	10%
Santhigam	40	100%	10	25%	75%
Tharpagam	0	0%	0	0%	0%



Inference:

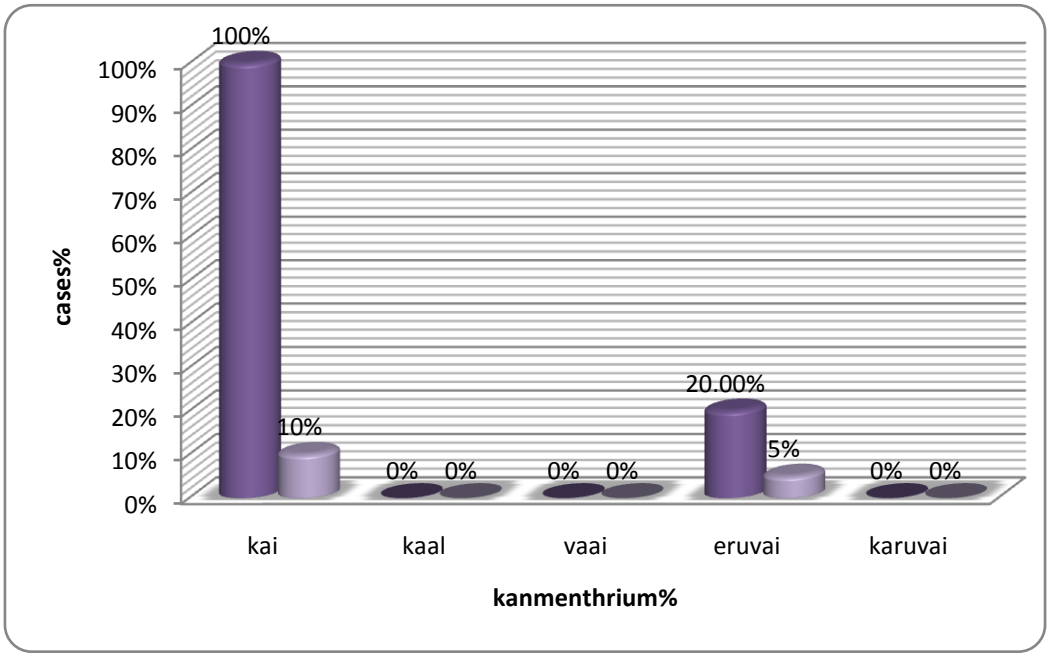
Santhigam was affected in all the 40 patients. After treatment 30 got relieved.

Bhothagam and klethagam is affected in 5 cases.klethagam is present in 2 cases and bhothagam is present in 1 case after treatment.

KANMENTHIRIYAM:

TABLE:13

KANMENTHIRIYAM	PATIENTS AFFECTED				PATIENTS RELIEVED FROM SYMPTOMS
	BEFORE TREATMENT	%	AFTER TREATMENT	%	
Kai	40	100%	4	10%	80%
Kaal	0	0%	0	0%	0%
Vai	0	0%	0	0%	0%
Eruvai	8	20%	2	5%	15%
Karuvai	0	0%	0	0%	0%



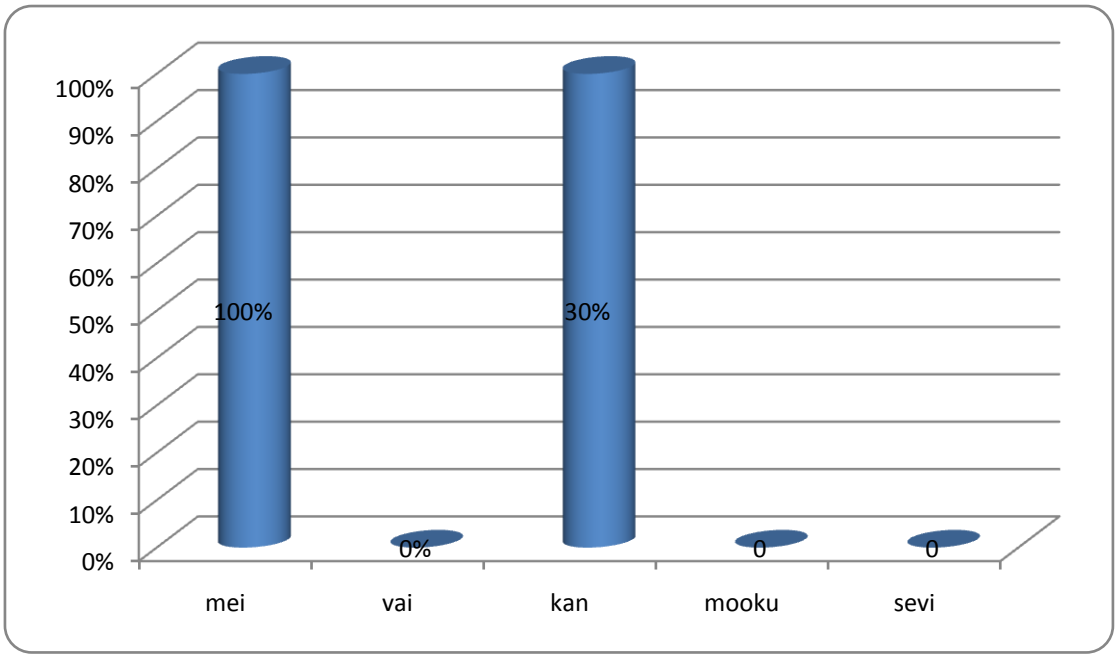
Inference:

Kai was affected in all the 40 patients, 32 got relieved from symptoms after treatment. Eruvai was affected in 8 patients, 6 got relieved from symptoms after treatment .

DISTURBANCES IN GNANENTHRIYAM:

TABLE:14

SL.NO	GNANENTHRIYAM	NO OF CASES	PERCENTAGE
1	Mei	40	**100%**
2	Vai	0	0%
3	Kan	12	**30%**
4	Mooku	0	0%
5	Sevi	0	0%



INFERENCE:

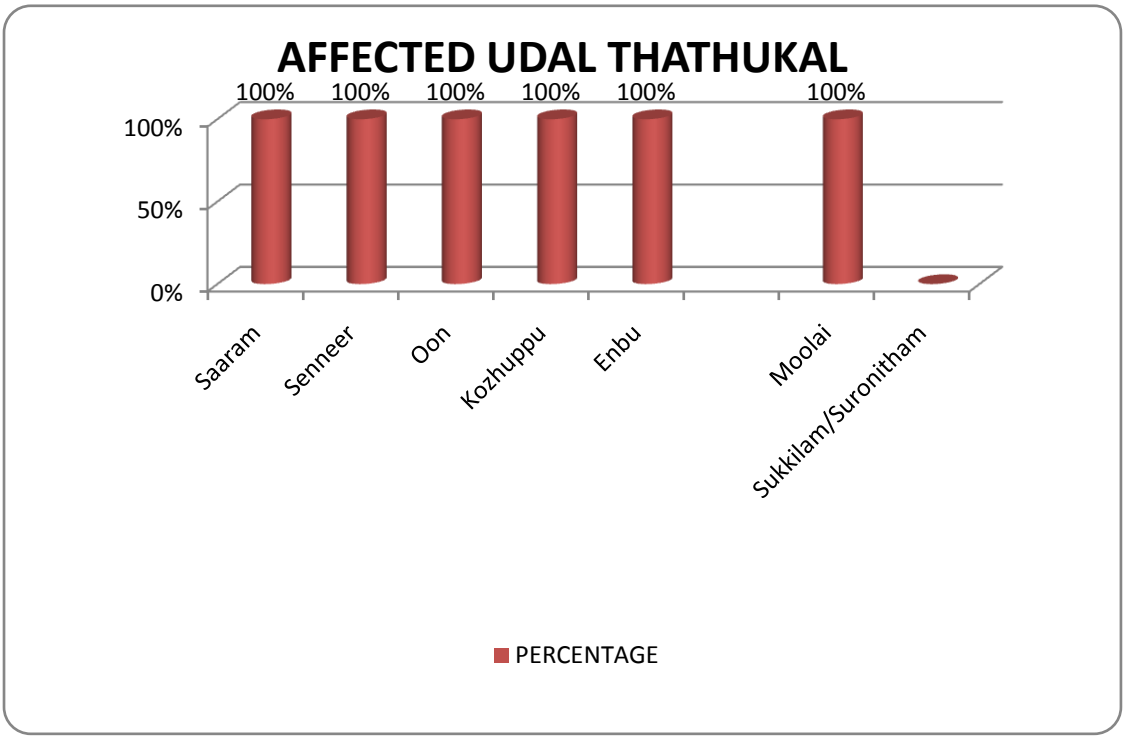
Mei (pain in neck and in upper limbs)is affected in all the 40 cases kan is affected in30% .

DISTURBANCE IN UDAL THATHUKKAL

TABLE:15

UDAL THATHUKKAL	NUMBER OF CASES	PERCENTAGE
Saaram	40	100%
Senneer	40	100%
Oon	40	100%
Kozhuppu	40	100%
Enbu	40	100%
Moolai	40	100%

Sukkilam/Suronitham	Nil	Nil



INFERENCE:

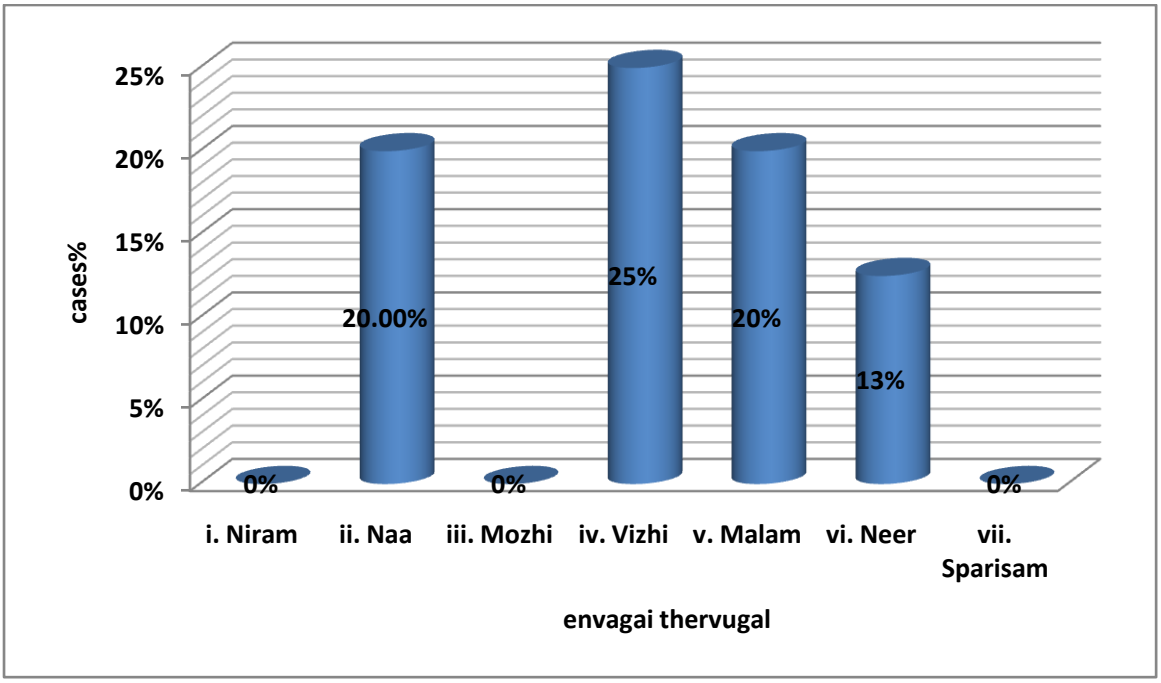
Saaram, Senneer, Oon, Kozhuppu, Enbu, Moolai were affected in all the 40 cases .

ENVAGAI THERVUGAL:

TABLE:16

ENVAGAI THERVUGAL	*PATIENTS*	
	AFFECTED	**PERCENTAGE**
i. Niram	0	0%
ii. Naa	8	20%
iii. Mozhi	0	0%
iv. Vizhi	10	25%
v. Malam	8	20%
vi. Neer	5	12.5%

vii. Sparisam	0	0%



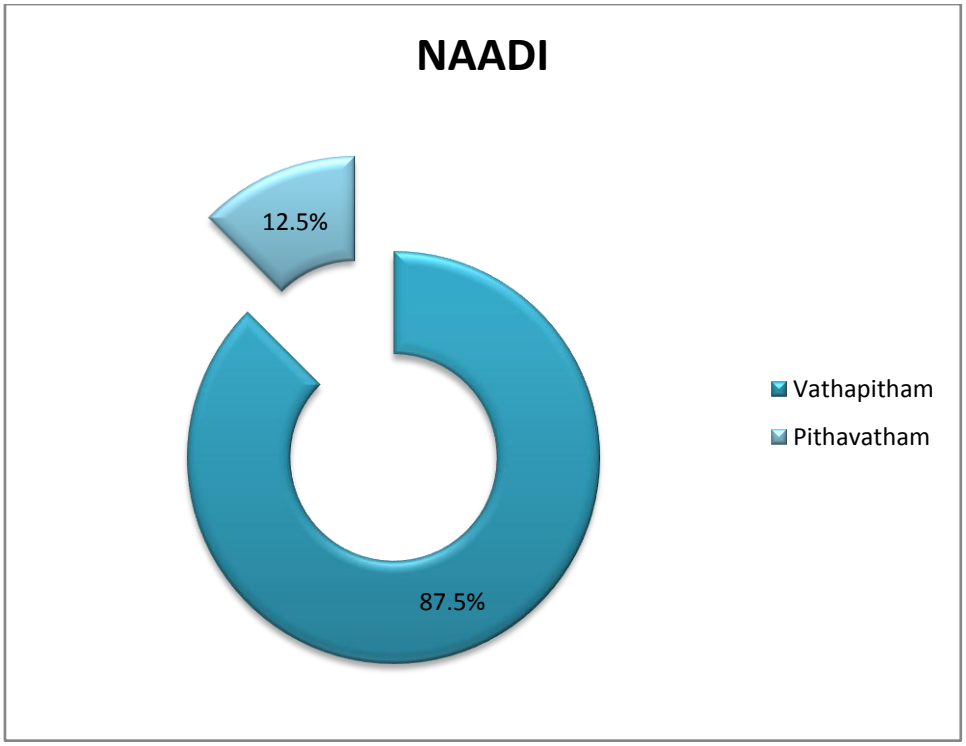
OBSERVATION: Among 40 patients 25% vizhi is affected and 20% of naa and malam is affected.

There was no change in Niram, Mozhi and Sparisam

a. NAADI

TABLE:17

NAADI	NUMBER OF CASES	PERCENTAGE
Vathapitham	**35**	**87.5%**
Pithavatham	5	12.5%
Total	40	100%



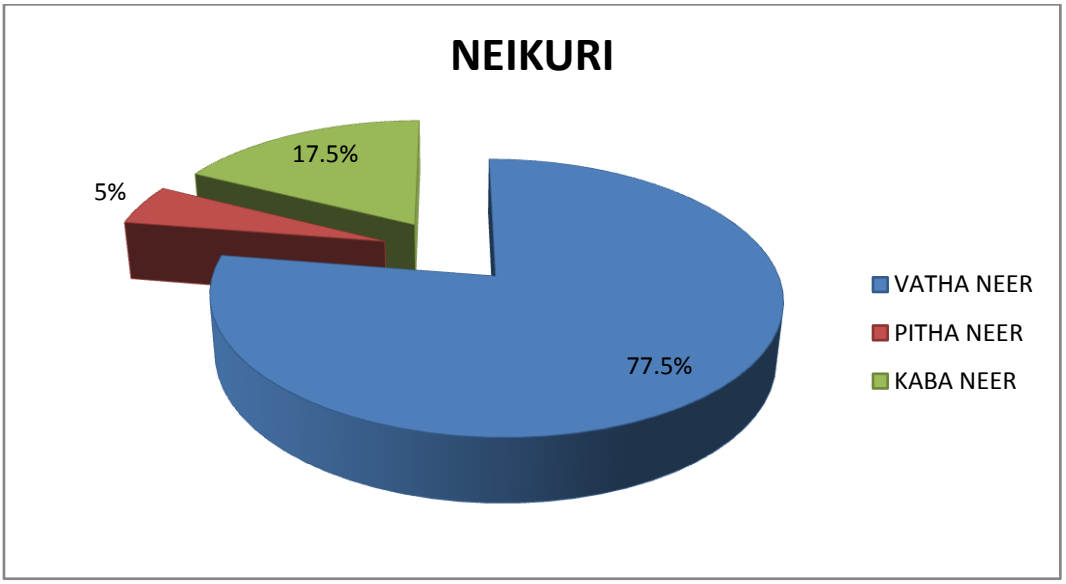
Inferance: Majority of the cases 35 (87.5%) revealed Vatha Pitha naadi.

NEIKKURI (Oil on urine sign)

TABLE:18

SPREADING PATTERN	NUMBER OF CASES	PERCENTAGE
Aravenaneendathu Vathaneer (Spreading like a snake)	31	**77.5%**
Aazhipolparaviathu Pitha neer (Spreading like a ring)	2	5%

Muththothu Ninrathu Kabaneer (Stands like a pearl)	7	**17.5%**
Total	40	100



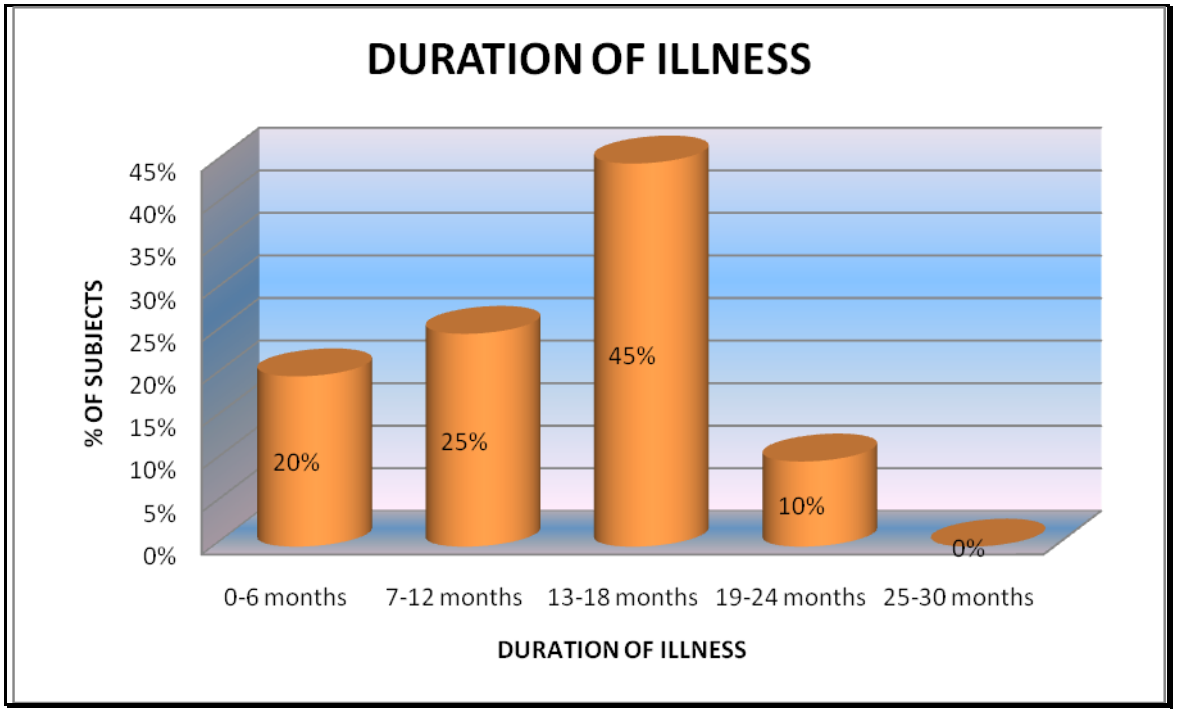
Observation: Among the 40 cases 31 (77.5%) cases had Vatha neer in majority

DURATION OF ILLNESS:

TABLE:19

DURATION OF ILLNESS	*PATIENTS*	
	NO.	**PERCENTAGE**
Up to 6 months	8	20%
7 – 12 months	10	25%
13 –18 months	18	**45%**

19 – 24 months	4	10%
25 – 30 months	-	0
Total	40	100%



Inference:

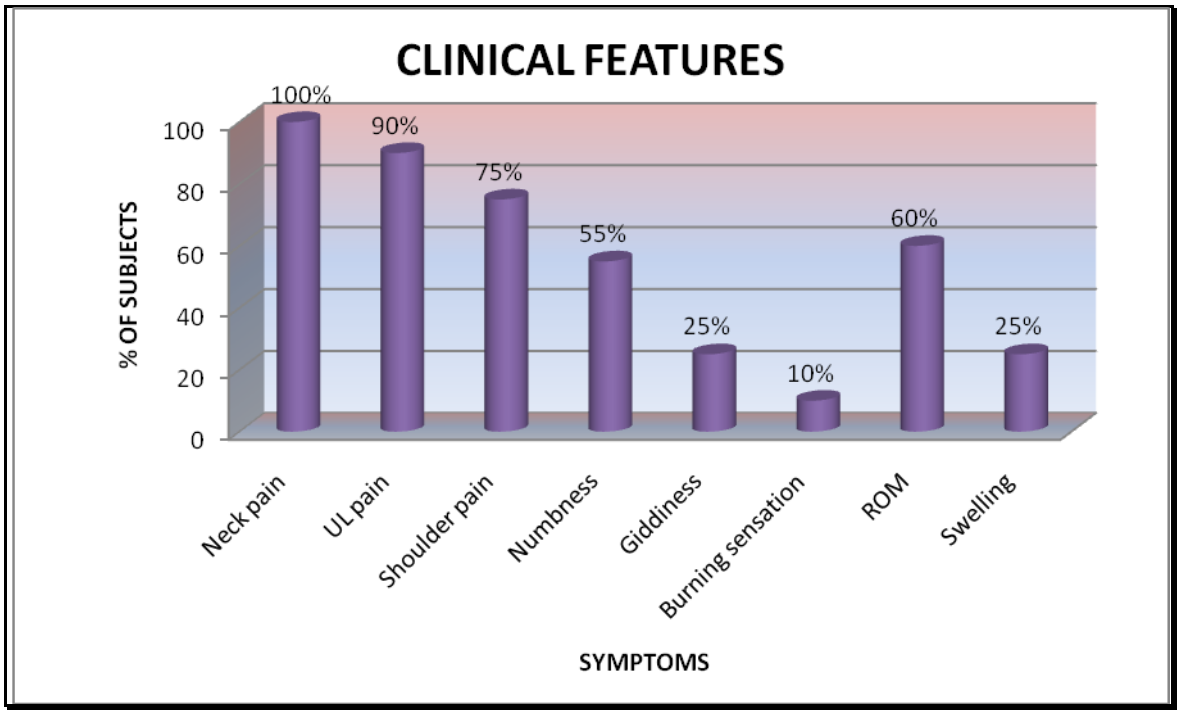
In about 18 cases(45%) duration of illness was 13-18 months,10 cases(25%)had illness for about 7-12 months,8 cases 20% patients had illness for less than 6months,4 cases(10%) patients had illness for 19-24 months.

CLINICAL FEATURES:

TABLE:20

Clinical Features	*PATIENTS*	
	No.	**Percentage**
Pain in neck	40	**100%**
Radiating pain in the upper limbs(UL)	36	**90%**
Radiating pain to the shoulders	30	**75%**

Numbness in upper limbs(UL)	22	55%
Giddiness	10	25%
Burning sensation in upper limbs(UL)	4	10%
Restriction of movements(ROM)	24	**60%**
Swelling	10	25%



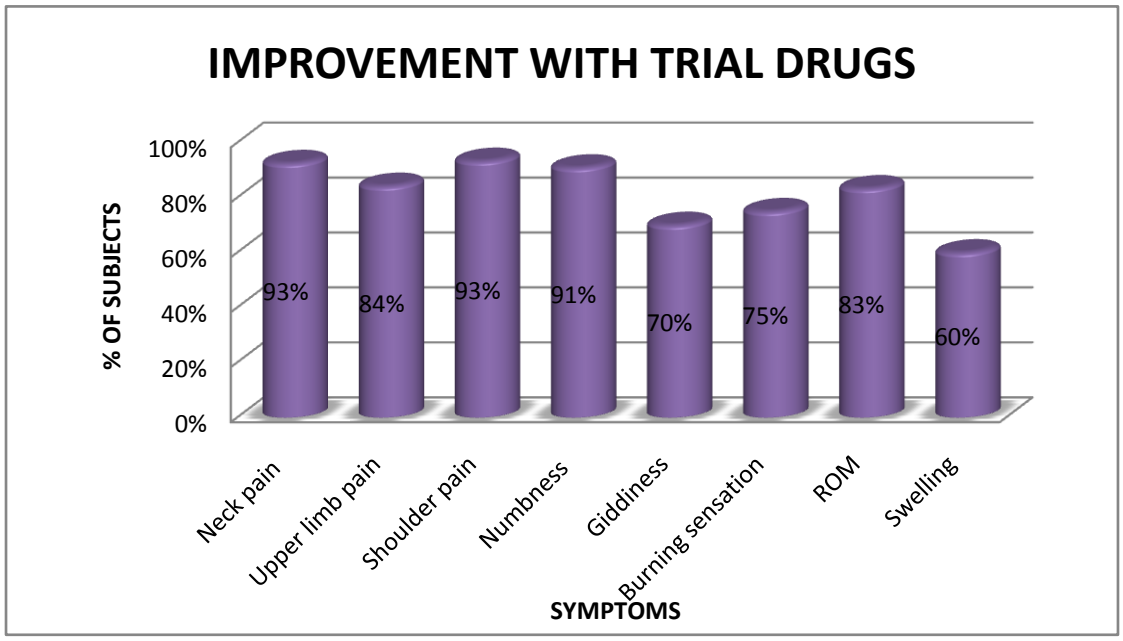
Inference: All 40 patients neck pain is present.radiating pain is present in90%,shoulder pain in 75%numbness in 55% giddiness in 25%burning sensation in 10%,restriction of movement in 60%,swelling in 25%.

PROGRESS:

TABLE 21

Clinical Features	***Patients***		
	Before Treatment	**Aftertreatment**	**% Of *Patients* Relieved From Symptoms**
Pain in neck	40	3	**92.5%**

Radiating pain in upper limbs	36	6	**84.2%**
Radiating pain to the shoulders	30	2	**93.3%**
Numbness in upper limbs	22	2	**90.9%**
Giddiness	10	3	70%
Burning sensation in upper limbs	4	1	75%
Restriction of movements	24	4	**83.33%**
Swelling	10	4	60%

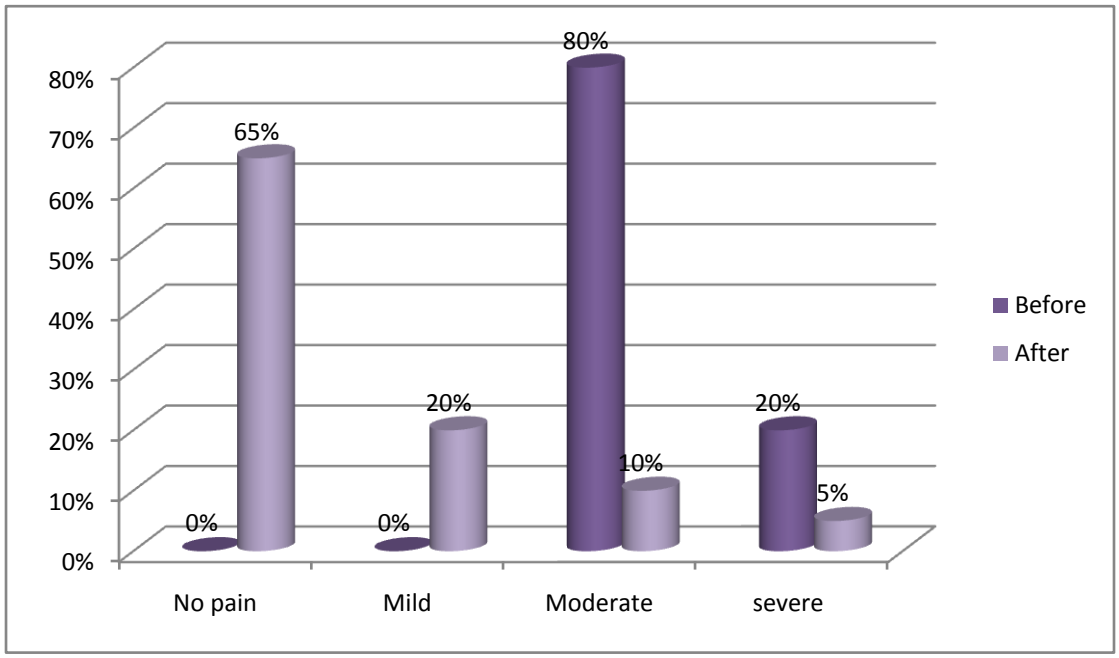


Inference:

Among 40 cases 92.5% are relieved from neck pain,84.2%relieved from radiating pain,93.3% relieved from shoulder pain, 90.9%relieved from numbness,70%relieved from giddiness,75% relieved from burning sensation,83.33%relieved from restrictations,60%relieved from swelling.

NATURE OF PAIN:

NATURE OF PAIN	No. of Patients			
	BEFORE TREATMENT	%	AFTER TREATMENT	%
NO PAIN	0	-	26	65 %
MILD	0	-	8	20 %
MODERATE	32	80%	4	10 %
SEVERE	8	20%	2	5 %
TOTAL	40	100%	40	100 %

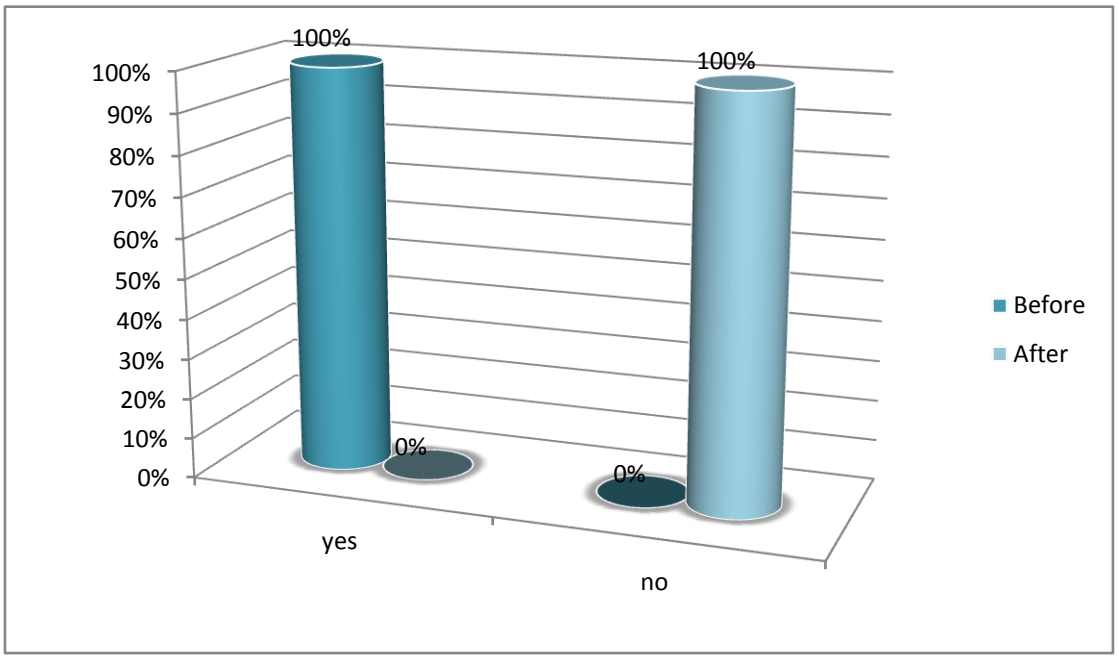


Inference:

Before treatment, 32 (80%) patients were affected by moderate pain, 8 patients were affected by severe pain. After treatment, 26 (65%) patients were found to be with no pain, 8(20%) patients with mild pain, 4(10%) patients with moderate pain and 2(5%) patients with no reduction in pain.

AGGRAVATING FACTOR ON MOVEMENT:

Aggravating factor on Movement	No. of Patients				Percentage of Patients Relieved
	BEFORE TREATMENT	%	AFTER TREATMENT	%	
Yes	40	100%	0	-	100%
No	0	-	40	100%	0%
Total	40	100%	40	100%	100%



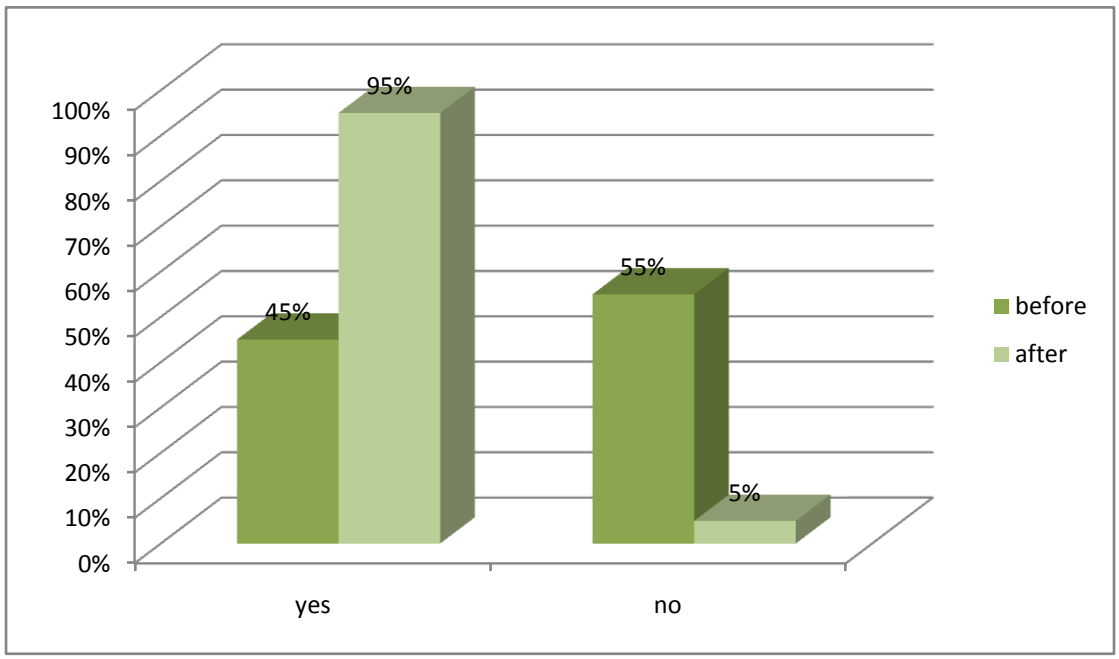
Inference:

Before treatment, all the 40 patients (100%) were affected by aggravating factor on movement. After treatment, all the 40 patients (100%) were relieved.

RELIEVING FACTOR – REST:

Relieving factor - Rest	No. of Patients			
	BEFORE TREATMENT	%	AFTER TREATMENT	%

Yes	18	45%	38	95%
No	22	55%	2	5%
Total	40	100%	40	100%



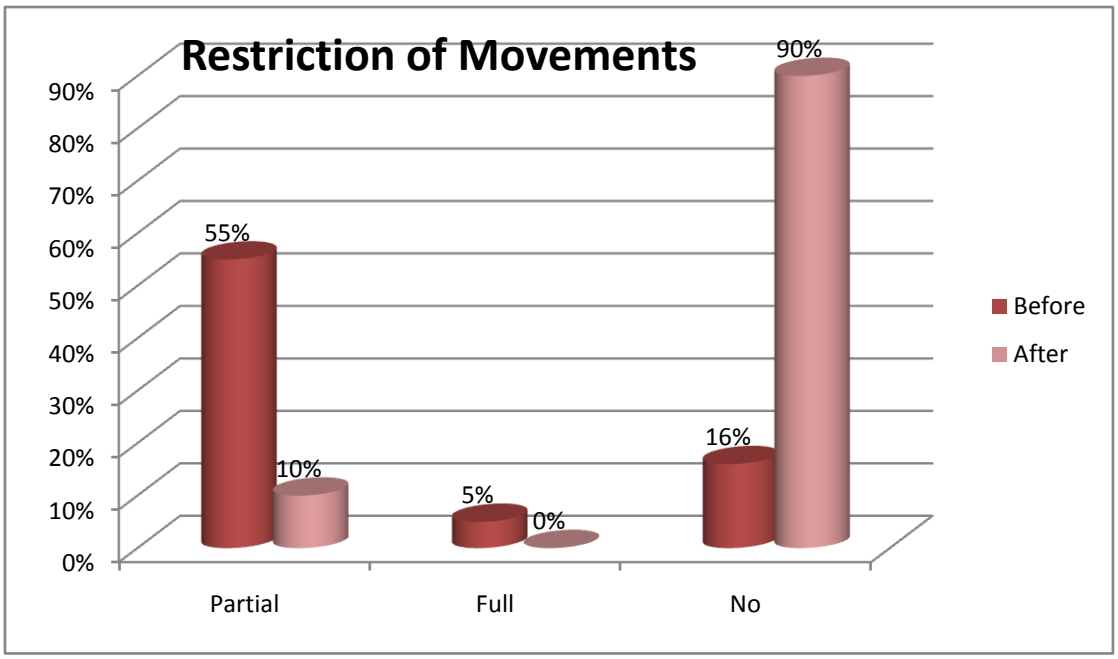
Inference:

Before treatment, 45%(18) patients were relieved during rest. After treatment, 38 patients (95%) were relieved during rest.

RESTRICTION OF MOVEMENTS:

Restriction of movements	No. of Patients			
	BEFORE TREATMENT	%	AFTER TREATMENT	%

Partial	22	55%	4	10%
Fully	2	5%	0	0%
No	16	40%	36	90%
Total	40	100%	40	100%



Inference:

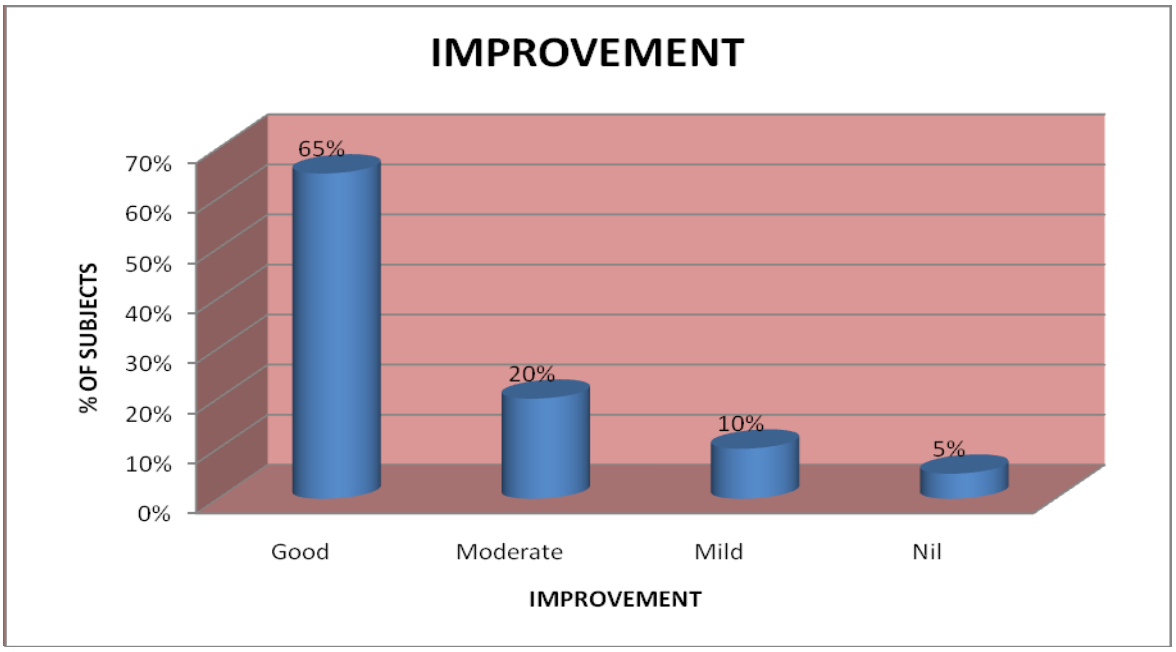
Before treatment 22(55%) patients had partial restriction and 2(5%) patients were restricted fully. After treatment only 4(10%) has partial restriction and remaining 36(90%) patients were relieved from restriction of movement.

RESULT:

Table22

RESULT	SUBJECTS

	NO. OF SUBJECTS	PERCENTAGE
Good	26	65%
Moderate	8	20%
Mild	4	10%
Nil	2	5%
Total	40	100%



Inference: Good improvement was seen in 65% of study subjects.

Moderate improvement was seen in 20% of study subjects.

Mild improvement was seen in 10% of study subjects.

No improvement was seen in 5% of study subjects.

STATISTICAL ANALYSIS

Mean and Standard deviation was used to test the significance of treatment using before and after treatment data on cervical spondylosis and Symptoms.

The level of significance probability 0.05 was used to test the treatment difference and the values are statistically significant.

ESR (1/2 AN HOUR)

ESR (1/2 an hour)	Mean	Std.Deviation	Std.Error Mean	t VALUE	p VALUE
Before treatment	**6.25**	**6.736**	**1.065**	**2.365**	**0.023**
After treatment	**4.60**	**3.177**	**0.502**		

ESR (1 HOUR)

ESR (1 HOUR)	Mean	Std.Deviation	Std.Error Mean	t VALUE	p VALUE
Before treatment	**16.55**	**18.031**	**2.851**	**2.186**	**0.035**
After treatment	**11.75**	**6.690**	**1.058**		

OBSERVATION: The statistical analysis reveals that there has been moderate significant reduction in ESR value after treatment.

PAIN ASSESSMENT SCALE BEFORE AND AFTER TREATMENT

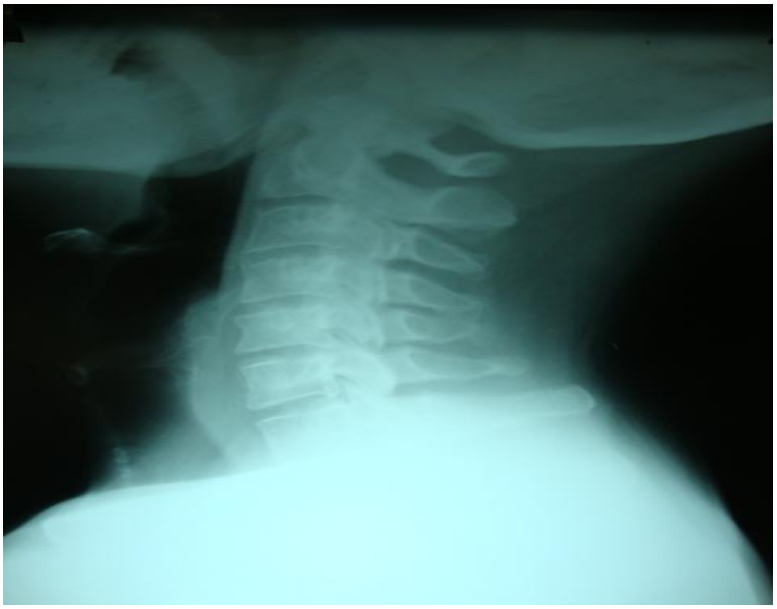
Pain Scale	Mean	Std.Deviation	Std.Error Mean	t VALUE	p VALUE
Before treatment	**5.65**	**1.424**	**0.225**	**24.085**	**P < 0.0001**
After treatment	**0.98**	**1.230**	**0.194**		

The mean± standard deviation of pain scale score at before and after treatment were 5.65 ± 1.424and 0.98 ± 1.230 respectively which is statistically highly significant (t= 24.0 p<0.0001) i.e. the symptoms have been reduced significantly after the treatment.

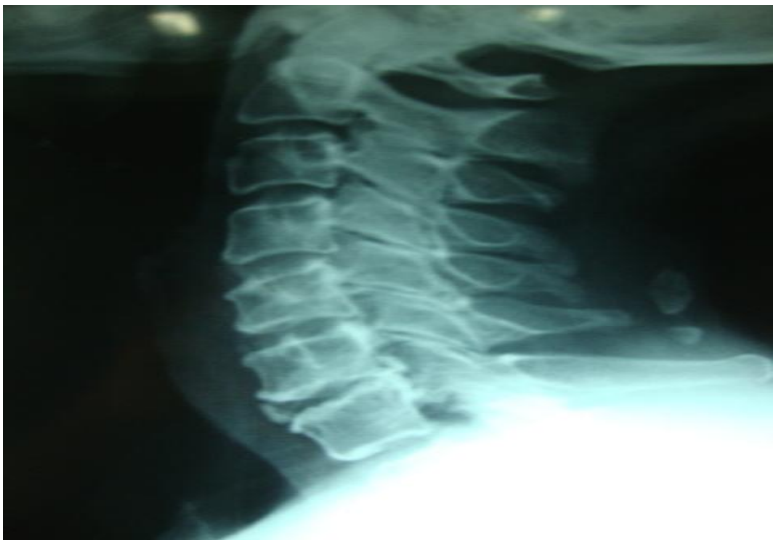
X-RAYS OF OPD AND IPD PATIENTS

XRAY SHOWING LOSS OF CERVICAL LORDOSIS

C099666 37/F



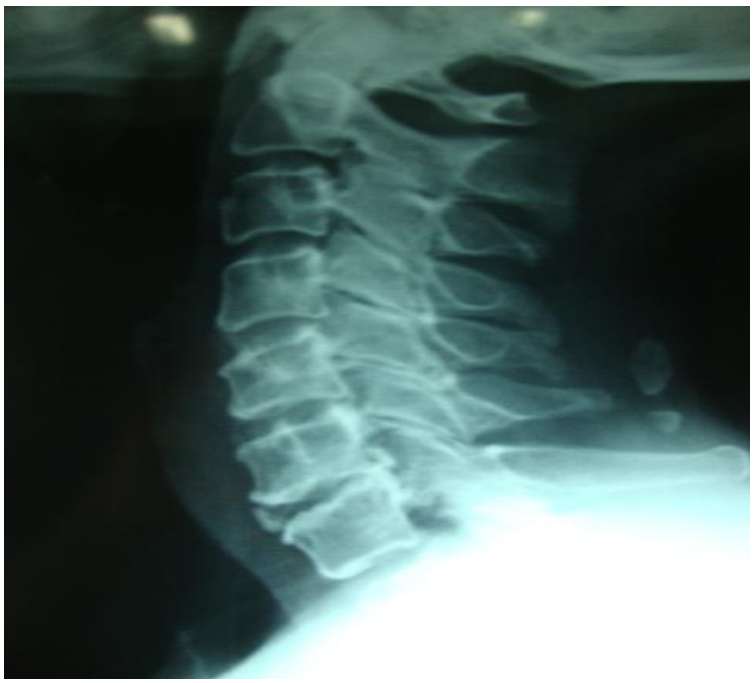
C96651 50/F



B55586 26/M

X-RAY SHOWING OSTEOPHYTES AT C6-C7

D004970 47/M



X-RAY SHOWING DEGERATIVE CHANGES AT

C3-C5 &OSTEOPYHTES AT C4-C5

IP4208 32/F

URINE INVESTIGATIONS

Sl.no	Op/ip .no	AGE	SEX	Albumin		Sugar		Deposits	
				BT	AT	BT	AT	BT	AT
1	C94873	29	M	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
2	C96984	50	M	Nil	Nil	Nil	Nil	2-5 epi.cells	2-3epi.cells
3	C93620	38	M	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
4	D004970	47	M	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells -
5	B55586	26	M	Nil	Nil	Nil	Nil	1-2 epi.cells, 3 pus cells	1-2 epi.cells,
6	D000205	48	M	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
7	D000425	37	M	Nil	Nil	Nil	Nil	2-3 epi.cells	2-3 epi.cells -
8	C099666	37	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
9	C96651	50	F	Nil	Nil	Nil	Nil	2-3 epi.cells	2 epi.cells
10	D004308	45	F	Nil	Nil	Nil	Nil	1-2 epi.cells	2-3 epi.cells
11	C098214	40	F	Nil	Nil	Nil	Nil	1-2 epi.cells 1-2 pus cells	1-2 epi.cells
12	C97940	48	F	Nil	Nil	Nil	Nil	2 epi.cells	2-4 epi.cells
13	C97647	33	F	Nil	Nil	Nil	Nil	2 epi.cells -	2 epi.cells -
14	C95513	40	F	Nil	Nil	Nil	Nil	3-6 epi.cells	2-4epi.cells
15	C97598	48	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
16	C94733	32	F	Nil	Nil	Nil	Nil	3-4 epi.cells, 4-6pus cells.	2-4 epi.cells
17	C96802	24	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
18	C95436	38	F	Nil	Nil	Nil	Nil	1-2 epi.cells, 2-4 pus cells	1-2 epi.cells, 2 pus cells
19	D000496	36	F	Nil	Nil	Nil	Nil	2 epi.cells	2-4 epi.cells
20	D000006	32	F	Nil	Nil	Nil	Nil	1-2 epi.cells	2-4 epi.cells

URINE INVESTIGATION

Sl.no	Op .no	Age	SEX	Albumin		Sugar		Deposits	
				BT	AT	BT	AT	BT	AT
1	C94833	26	F	Nil	Nil	Nil	Nil	2 epi.cells	3 epi.cells
2	C098191	40	F	Nil	Nil	Nil	Nil	3 epi.cells	2 epi.cells
3	D004664	42	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells -
4	C95550	36	F	Nil	Nil	Nil	Nil	2-6 epi.cells	2 epi.cells
5	C94392	31	F	Nil	Nil	Nil	Nil	3-6 epi.cells	4 epi.cells
6	C098014	32	F	Nil	Nil	Nil	Nil	1-2 epi.cells 2-4 pus cells	1-2 epi.cells
7	C098239	38	F	Nil	Nil	Nil	Nil	2-4 epi.cells	1-2 epi.cells -
8	D000836	25	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
9	C96489	31	F	Nil	Nil	Nil	Nil	2-5 epi.cells	2 epi.cells
10	C09925	47	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
11	4185	48	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
12	4228	32	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
13	4258	37	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
14	4267	42	F	Nil	Nil	Nil	Nil	3-5 epi.cells 4-6 pus cells	2-4 epi.cells
15	4255	48	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells -
16	4226	40	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
17	4208	42	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells -
18	4251	34	F	Nil	Nil	Nil	Nil	2-5 epi.cells	2 epi.cells
19	4175	42	F	Nil	Nil	Nil	Nil	4-6 pus cells	2 epi.cells -
20	5217	26	M	Nil	Nil	Nil	Nil	2 epi.cells	2 epi.cells

PAIN SCALE RATING IN OPD AND IPD CASES

S.No	Op /Ip no	AGE	SEX	Pain Scale Rating	
				BT	AT
1.	C94873	29	M	6	0
2.	C96984	50	M	6	2
3.	C93620	38	M	4	0
4.	D004970	47	M	4	0
5.	B55586	26	M	8	1
6.	D000205	48	M	6	0
7.	D000425	37	M	8	4
8.	C099666	37	M	6	0
9.	C96651	50	F	6	2
10.	D004308	45	F	6	0
11.	C098214	40	F	4	0
12.	C97940	48	F	4	0
13.	C97647	33	F	6	0
14.	C95513	40	F	4	0
15.	C97598	48	F	4	4
16.	C94733	32	F	6	0
17.	C96802	24	F	6	2
18.	C95436	38	F	4	0
19.	D000496	36	F	4	0
20.	D000006	32	F	6	2

PAIN SCALE RATING

S.No	NAME (Ip patients and op patients)	AGE	SEX	Pain Scale Rating	
				BT	AT
1.	C94833	26	F	6	0
2.	C098191	40	F	8	4
3.	D004664	42	F	4	0
4.	C95550	36	F	6	2
5.	C94392	31	F	6	0
6.	C098014	32	F	4	0
7.	C098239	38	F	4	0
8.	D000836	25	F	6	0
9.	C96489	31	F	6	2
10.	C09925	47	F	4	0
11.	4185	48	F	6	0
12.	4228	32	F	8	2
13.	4258	37	F	4	0
14.	4267	42	F	6	0
15.	4255	48	F	4	0
16.	4226	40	F	4	4
17.	4208	42	F	6	0
18.	4251	34	F	8	6
19.	4175	42	F	6	0
20.	5217	26	F	4	2

RADIOLOGICAL FINDINGS OF CERVICAL SPINE [AP & LATERAL VIEW]

Sl. No	OP/IP NO	Age	Sex	Cervical Lordosis		IVD space narrowing		Degenerative changes		Osteophytes	
				BT	AT	BT	AT	BT	AT	BT	AT
1.	C94873	29	M	Lost	Lost	C4-6	C4-6	C4-6	C4-6	C4-6	C4-6
2.	C96984	50	M	N	N	C4-5,C5-6	C4-5,C5-6	C4-7	C4-7	C4-7	C4-7
3.	C93620	38	M	N	N	C3-4,C4-5	C3-4,C4-5	C4-6	C4-6	C4-6	C4-6
4.	D004970	47	M	N	N	C2-3,C3-4	C2-3,C3-4	All	All	All	All
5.	B55586	26	M	Lost	Lost	C4-5,C5-6	C4-5,C5-6	C4-7	C4-7	C4-7	C4-7
6.	D000205	48	M	N	N	C4-5,C5-6	C4-5,C5-6	C4-7	C4-7	C4-7	C4-7
7.	D000425	37	M	N	N	C3-5,C5-6	C3-5,C5-6	C3-6	C3-6	C3-6	C3-6
8.	C099666	37	F	N	N	C4-5,C5-6	C4-5,C5-6	C4-6	C4-6	C5-6	C5-6
9.	C96651	50	F	N	N	C5-6,C6-7	C5-6,C6-7	C5-7	C5-7	C5-6	C5-6
10.	D004308	45	F	N	N	C3-4,C4-5	C3-4,C4-5	C3-5	C3-5	C3-4	C3-4
11.	C098214	40	F	N	N	C4-5	C4-5	C4-5	C4-5	C4-5	C4-5
12.	C97940	48	F	N	N	C3-4,C4-5,	C3-4,C4-5,	C3-5	C3-5	C4-5	C4-5
13.	C97647	33	F	N	N	C2-5	C2-5	C3-5	C3-5	C3-5	C3-5
14.	C95513	40	F	N	N	C4-6	C4-6	C5-6	C5-6	C5-6	C5-6
15.	C97598	48	F	N	N	C3-4,C4-5	C3-4,C4-5	C4-5	C4-5	C4-5	C4-5
16.	C94733	32	F	N	N	C3-6	C3-6	C4-6	C4-6	C4-6	C4-6
17.	C96802	24	F	N	N	N	N	C4-5	C4-5	C4-5	C4-5
18.	C95436	38	F	N	N	C5-6,C6-7	C5-6,C6-7	C3-7	C3-7	C3-7	C3-7
19.	D000496	36	F	N	N	C4-6	C4-6	C5-6	C5-6	C5-6	C5-6
20.	D000006	32	F	N	N	C3-4,C4-5	C3-4,C4-5	C4-5	C4-5	C4-5	C4-5

RADIOLOGICAL FINDINGS OF CERVICAL SPINE [AP & LATERAL VIEW]

Sl. No	OP/IP No:	Age	Sex	Cervical Lordosis		IVD space narrowing		Degenerative changes		Osteophytes	
				BT	AT	BT	AT	BT	AT	BT	AT
1.	C94833	26	F	Lost	Lost	C3-4,C4-5	C3-4,C4-5	C3-6	C3-6	C3-6	C3-6
2.	C098191	40	F	N	N	C5-6	C5-6	C4-6	C4-6	C4-6	C4-6
3.	D004664	42	F	Lost	Lost	C3-5	C3-5	C4-5	C4-5	C4-5	C4-5
4.	C95550	36	F	Lost	Lost	N	N	C3-4	C3-4	C3-4	C3-4
5.	C94392	31	F	N	N	C3-4	C3-4	C4-5	C4-5	C4-5	C4-5
6.	C098014	32	F	N	N	N	N	C4-5	C4-5	C4-5	C4-5
7.	C098239	38	F	N	N	C4-5,C5-6	C4-5,C5-6	C4-6	C4-6	C5-6	C5-6
8.	D000836	25	F	N	N	N	N	C4-6	C4-6	N	N
9.	C96489	31	F	N	N	N	N	C3-5	C3-5	C3-5	C3-5
10.	C09925	47	F	N	N	C3-7	C3-7	C4-6	C4-6	C4-6	C4-6
11.	4185	**48**	F	N	N	N	N	C5-6	C5-6	N	N
12.	4228	**32**	F	N	N	C4-5, C5-6	C4-5, C5-6	C4-6	C4-6	C4-6	C4-6
13.	4258	**37**	F	N	N	C3-4,C4-5	C3-4,C4-5	C3-5	C3-5	C3-5	C3-5
14.	4267	**42**	F	N	N	N	N	C4-5	C4-5	C4-5	C4-5
15.	4255	**48**	F	N	N	C5-6	C5-6	C4-6	C4-6	C4-6	C4-6
16.	4226	**40**	F	N	N	C3-6	C3-6	C3-6	C3-6	C4-6	C4-6
17.	4208	**42**	F	N	N	N	N	C3-4	C3-4	C3-4	C3-4
18.	4251	**34**	F	N	N	C5-6	C5-6	C4-6	C4-6	C4-6	C4-6
19.	4175	**42**	F	N	N	N	N	C4-6	C4-6	C4-6	C4-6
20.	**5217**	**26**	M	N	N	N	N	C4-5	C4-5	C5-6	C5-6

DISCUSSION

- The main aim of the treatment was to study the therapeutic effect of the drug kariuppu chenduram (int) and kunthirika thylam(ext). The clinical features of ceganavatham can be correlated to cervical spondylosis in Modern science. As per yougi vaithiya chinthamani text, Pain below the neck, above the hip and in both upper limbs,Scorpion sting like pain in the above regions,Heaviness of the body,Burning sensation of the eyes,Constipation is present.

- The safety of the trial drug usage and standardization of the trial drug through biochemical analysis were also ensured during the study.

- The drug was prepared in the Gunapadam lab of National Institute of Siddha after the authentication of the raw drugs by the concerned department. The trial drug was prepared by the standard operating procedure as mentioned in the protocol.

- The preclinical toxicity studies (Acute and sub acute toxicity) for the above said trial drug was conducted at National Institute of Siddha after getting the proper acceptance and permission from the Institutional Animal Ethical Committee (IAEC) **(1248/ac/09/CPCSEA/december/ 2011)**

- The trial drug was proved to be safe for human beings from the observations made from the study .

- The biochemical qualitative and quantitative analysis were done at the biochemistry lab of NIS and IIT Chennai respectively. It revealed the presence of effective minerals and the existence of the drug molecules at micro level.
- The clinical study was conducted with a well defined protocol and a proper proforma after the approval of the Institutional Ethical Committee (IEC). After screening 60 cases reporting at the OPD of department of Maruthuvam , 40 cases were selected for induction to the trial. Before enrollment into the trial the informed consent was obtained from the patients.

- The patients were treated for a period of 48 days with kariuppu chenduram (int)260mg bd with honey and kunthirika thylam (ext).Clinical assessment was done during each visit in OPD patients (12days once) and daily for IPD patients and the data were noted in the prescribed proforma.
- Laboratory investigations,x-ray and ecg were done on the 0day, & 48th day of the trial for both OP & IP patients. For IP patients, who was not in a situation to stay in the hospital for a long time was advised to attend the OPD for the continuation of the treatment.All the patients were put under observation for 2 months follow up period without the trial drug treatment.

THE OBSERVATIONS DISCUSSED BELOW:

GENDER DISTRIBUTION

The majority affected sex was male i.e, 8 cases (20%) and female was 32cases (80%)

AGE DISTRIBUTION

This study showed that the highest incidence of ceganavatham was between 31 – 40 years of age, i.e. 20 cases (50%). This may due to the work load.

GUNAM DISTRIBUTION

All the 39 cases under this analysis were predominantly of Rasatha gunam and one case is of thamo gunam assessed from interrogation and other observations.

DIET

Among the 40 cases 38 cases (95%) were non-vegetarians.

DISTRIBUTION OF CASES BY PARUVAKAALAM (SEASONS)

In this study, 28 cases (70%) were reported in kaar kaalam, 12cases (30%) in koothir kaalam .

OCCUPATIONAL REFERENCES

In this study 37.5% people are home maker,22.5% are clerical job,17.5% are software professionels,tailors are 7.5% and 5% is driver ,teacher and coolie.

SOCIO-ECONOMIC STATUS:

In this study 35% of people is poor ,37.55% people is in lower middle class,17.5% of people is in lower middle class and rich peoples are 10%.

DERANGEMENTS OF VATHAM

Viyanan and samanan were affected in all the 40 cases (100%) .Uthanan is affected in 4 case and abanan is affected in 8 case.after treatmen 14 cases remain affected in viyanan and samanan.abanan and uthanan remain affected in 2 cases.

DERANGEMENT OF PITHAM

Saathaga piththam was affected in 30 patients, analagam is affected in 8 cases,ranjagam is affected in 10 cases, prasagam is affected in 4 cases.after treatment 2 cases 2 cases remain affected renjagam is remain affected in 8 cases,sathagam is affected in 4 cases.

DERANGEMENT OF KABAM

Santhigam is affected in almost all the patients 100%.klethagam and pothagam is affected in 5 cases.after treatment klethaaagam is affected in 2 cases pothagam is in 1 case and santigam remain affected in 10 cases.

DERANGEMENT OF GNANENTHIRIUM

Mei is affected in all the 40 cases 100% kan is affected in 30% due to age factor.

DISTRIBUTION OF UDAL THATHUS

All the udal thathus are affected except sukkilam and suronitham.

DISTRIBUTION OF CASES BY EN VAGAI THERVU

Naa is affected in 30%,vizhi is affected in 10 cases,malam is affected in 20%,neer is affected in 12.5%.

DISTRIBUTION OF CASES BY NAADI

87.5% of cases have vathapitham and 12.5% of cases have pithavatham.

DISTRIBUTION OF CASES BY NEIKKURI

Vathaneer is in 77.5% patients,17.5% have kabha neer and 5% have pitha neer.

CLINICAL FEATURES.

Among 40 subjects of the trial 100% subjects reported with pain in nape, 80% with radiating pain in upper limbs, 70% reported radiating pain in shoulders, 50% reported numbness in upper limbs, 17.5% with giddiness, 7.5% with burning sensation in upper limbs , 55% reported restriction of movements, 25% with swelling

LABORATORY INVESTIGATION:

Laboratory investigation of blood and urine were done for all 40 subjects prior to and after trial. There were no significant changes in the parameters. Pre-treatment and post-treatment results of Liver function tests and renal function tests were normal.

X-RAY FINDINGS

The radiographic studies of the subjects showed narrowed joint space and presence of osteophytes. The trial drug showed reduction in clinical signs and symptoms rather than any changes in radiographic studies.

The treatment was aimed to normalize the deranged kuttram and to provide relief from symptoms. Before treatment the patients were advised to take Agasthiyar Kuzhambu-130 mgs with palm jaggery, during early morning for purgation followed by rest on that day. The next day onwards treatment with the trial drugs kariuppu chenduram(internal) and kunthirika thailam (external) was started. During treatment, the subjects were advised to follow pathiyam (diet restrictions), to avoid lifting heavy weights and to avoid adopting postures involving prolonged neck flexion.

After treatment, 92.5% subjects were relieved from pain in nape, 84.2% from radiating pain in upper limbs, 93.3% from radiating pain in shoulders, 90.9% from numbness

in upper limbs, 70% from giddiness, 75% from burning sensation in upper limbs, 83.33% from restriction of movements, 60% from swelling.

Primary outcome:

Effect of trial drugs in reducing pain in ceganavatham was statistically significant.

92.5% subjects among 40 had reduction in neck pain, 84.2% among 38 had reduction in radiating pain in upper limbs and 93.3% among 30 had reduction in radiating pain in shoulders post-treatment.

Secondary outcome:

Effect of trial drugs in reducing restriction of movements in ceganavatham was good.

83.33% among 24 had reduction in restriction of movements post-treatment.

IMPROVEMENT:

- Good improvement in 26 subjects,
- Moderate improvement in 8 subjects,
- Mild improvement in 4 subjects and
- No improvement in 2 subjects.

were reported in study subjects.

STATISTICAL ANALYSIS:

I. PAIN ASSESSMENT SCALE BEFORE AND AFTER TREATMENT.

BIO STATISTICAL ANALYSIS

The clinical trials of the drug **KARIUPPU CHENDURAM**(internal)and **KUNTHIRIKA THYLAM**(External) are differentiated in terms of percentages. The effectiveness of the drug is assessed by using paired comparison test (paired t test). The responses (intensity of pain) of the patients to the drug are analyzed.

Assessment of the effectiveness of drug:

The effectiveness of the drug was assessed by the relief of the patients from pain, and which is measured using a standard pain scale.

INFERENCE: The test drug is is **highly statistically significant (p<0.0001)** and hence effective in reducing the pain

ACUTE ORAL TOXICITY STUDY

Kariuppu chenduram at the dose of 9.36mg/kg/bw did not exhibit any mortality in mice. In Necropsy, the organs of the animal such as, Liver, Heart, Lungs, pancreas Spleen, Stomach, Intestine, Kidney, Urinary bladder, Uterus all appeared normal.

LONG TERM TOXICITY STUDY

Kariuppu chenduram at the dose of 93.6mg/kg/bw (10x) did not exhibit any mortality in rats. Biochemical parameters and histopathology report were also normal. There were no signs of toxicity.

SUMMARY

- The aim of the study was to evaluate the efficacy of the drug kariuppu chenduram (int) and kunthirika thylam(ext) Before initiating the clinical trial, approval was got from the Institutional Animal Ethical Committee and Institutional Ethical Committee for conducting the pre clinical studies and clinical studies respectively by submitting the well defined protocol and proforma.
- The raw drugs were authenticated by the concerned department and the trial drug was prepared by the investigator in the Gunapadam lab of National Institute of Siddha as per the Standard Operating Procedure mentioned in the protocol.
- The medicine was then subjected to pre clinical toxicity studies (Acute and long term toxicity studies) as per the protocol and the safety of the drug was ensured.
- From the Acute oral toxicity study, the trial drug was found to be safe even at higher dose level **of 9.36**mg/kg/bw.
- From the Long term toxicity study the trial drug at the dose of 93.6mg/kg/bw (10x) did not exhibit any mortality in rats.
- The qualitative and quantitative bio chemical studies were done at the bio chemistry lab of National Institute of Siddha and IIT Chennai respectively.
- The biochemical study of the trial drug reveals the presence of **iron,calcium,sulphate and phosphate.,**Among the 60 cases screened at the OPD of department of Maruthuvam NIS, 40 cases were recruited for the trial as per the inclusion and exclusion criteria.
- Clinical diagnosis of ceganavatham was made by Siddha and Modern methodology.
- Before inducement into the trial informed consent was obtained from the patients. Out of the 40 cases 30 cases were treated in OPD and 10 cases in IPD.

- The patients were treated for a period of 48 days The trial medicine selected for Internal treatment were kariuppu chenduram 260mg bd with honey referred under Siddha literature anuboga vaithhhya navaneetham part-3and kunthirika thylam external under siddha pharmacoepoeia..Required lab investigations were carried out before and after the treatment and the concerned data was recorded in the proforma.
- Clinical assessment was done daily in all the IP patients and in OP patients it was assessed once in 12days.
- During the study period, there was no event of any adverse reactions owing to the drug or disease.
- Statistical analysis showed significant difference between before and after treatment in
- Good improvement was observed in 26 subjects, moderate improvement in 8 subjects, mild improvement in 4 subjects and no improvement was observed in 2 subjects . Effect of trial drugs in reducing restriction of movements in ceganavatham was good.

CONCLUSION

- The safety studies (Acute toxicity and Long term toxicity) studies conducted revealed that the trial drug was safe even at higher dosage of 93.6mg/animal. There were no abnormalities found in blood investigation and histopathological examination .Hence it can be reasonably assumed that the drug is safe for human.
- Clinical study revealed the therapeutic efficacy of the trial drug by showing,
- 65% of subjects had good improvement, 20% had moderate improvement, 10% had mild improvement and 5% had no improvement.
- There were no adverse reactions complained during the trial.
- Statistical analysis showed significant difference between before and after treatment in the pain scale reading ($p < 0.0001$).
- Pharmacological studies of the trial drug kariuppu chenduram(internal) and kunthirika thailam (external) have shown significant anti- inflammatory and analgesic effects. The acute and chronic toxicity studies have shown no renal and hepato toxicity. Hence the trials drugs are very safe and effective.
- Thus it is concluded that are effective in reducing pain, numbness, swelling and restriction of movements in ceganavatham.

ANNEXURE - I

TOXICOLOGICAL EVALUVATION OF KARIUPPU CHENDURAM

ACUTE TOXICITY STUDY OF KARIUPPU CHENDURAM

[WHO guidelines, 1993]

Principle:

Acute toxicity was carried out in Swiss albino mice with a single exposure of 10 times of the recommended therapeutic dose of test compound the study duration will be 14 days.

Animal species **:** Swiss albino mice

Age / Weight / Size **:** 6 weeks. Mice-20-25gms.

Gender **:** Both male and female

Number of Animals **:** Mice: 20

Acclimatization Period **:** 7 Days

Clinical dose **:** 260 mg/day

S.No	Group	No of mice
1	Vehicle control	10 (5 male, 5 female)
2	Toxic dose 10X therapeutic dose (9.36mg)	10 (5 male, 5 female)

Test Animals

Test animals were obtained from the animal laboratory of the King institute, Chennai and stocked at National institute of siddha, Chennai. All the animals were kept under standard environmental condition (27+ or – 2 degree c).The animals had free access to water

and standard pellet diet (Sai Durga foods pvt.ltd, Bangalore).The principles of laboratory animal care were followed and the Institutional ethical committee approved the use of animals and the study design. **(1248/ac/09/CPCSEA/december/ 2011)**

Route of administration:

Oral route was selected, because it is the normal route of clinical administration.

Test substance and vehicle

The kariuppu chenduram is LIGHT BROWN in colour with mild odour. The test substance is insoluble in water, in order to obtain and ensure the uniformity in drug distribution the drug is dissolved by aqueous Tween 80 solution (10%).

Administration of doses

kariuppu chenduram was suspended in aqueous Tween 80 solution (10%), with uniform mixing and it was administered to the groups in a single oral dose .The control groups were received equal volume of the vehicle. The animals were weighed before giving the drug. The dose level was calculated according to body weight, and surface area. Since the clinical dose was 260mg/day it was converted to animal dose (9.36mg) and then administered. The principle of laboratory animal care was followed.

Observations

Observations were made and recorded systematically and continuously observed as per the guideline after substance administration. Animals were observed individually (visual observations included skin changes, alertness, grooming, aggressiveness, sensitivity to sound, touch and pain ,restlessness, tremors, convulsion, righting reflex, corneal reflex, gripping reflex, pinna reflex, writhing reflex, papillary reflex, urination, salivation, lacrimation for first 4 hrs, then periodically during the first 24 hrs. Animals were observed for body weight and mortality for 14 days. If animals dying during the period of study, the animals were sacrificed. At the end of the 14^{th} day all animals were sacrificed and necropsy was done.

Body Weight

Individual weight of animals was determined before the test substance was administered and daily for 14 days. Weight changes were calculated and recorded. At the end of the test, surving animals were weighed and sacrificed.

Results: kariuppu chenduram at the dose 9.36mg/animal did not exhibit any mortality in mice.

No behavior changes were noted for the first 4 hours and for the next 24 hours and throughout the study period of 14 days. No weight reduction was noted before and after the acute study duration. Reflexes were found to be normal before and after the study. All other observations were found to be normal before and after the study. In Necropsy, the organs of the animal such as, Liver, Heart, Lungs, Pancreas, Spleen, Stomach, Intestine, Kidney, Urinary bladder, Uterus all appeared normal.

SUB ACUTE TOXICITY STUDY OF KARIUPPU CHENDURAM

Animals	**:**	Male and Female Wister albino rats
Age	**:**	6-8 weeks
Weight	**:**	150-200 gms
Gender	**:**	Both male and female
Number of animals	**:**	Rat: 40
Acclimatization period	**:**	7 Days
Clinical dose	**:**	260mg/day
Clinical duration	**:**	28 days

S.No	Group	No of Rats
1	Vehicle control	10 (5male,5 female)
2	1XTherapeutic dose (9.36mg)	10 (5male,5 female)
3	5XTherapeutic dose (46.8mg)	10 (5male,5 female)
4	10XTherapeutic dose(93.6mg)	10(5male, 5 female)

Animal source:

Test animals were obtained from the animal laboratory of the King institute, Chennai, and stocked at national institute of siddha, chennai. All the animals were kept under standard environmental condition (27+ or – 2 degree c) .The animals had free access to water and standard pellet diet (Sai durga foods pvt.ltd, Bangalore). The principles of laboratory animal care were followed and the Institutional ethical committee approved the use of animals and the study design. **(1248/ac/09/CPCSEA/DECEMBER/IAEC 2011)**

Identification of animal:

By cage number, animal number and individual marking on fur.

Housing and Environment:

The animals were housed in polypropylene cages provided with bedding of husk. Dark and light cycle each of 12 hours.

Administration period:

The period of administration of the test substance to animals are depending on the expected period of clinical use. Since the clinical duration of the test drug is 28 days and as per WHO guidelines the administration period is reported to be 1 month.

Dose selection:

The results of acute toxicity studies in Swiss albino mice indicated that karpoora silasathu parpam was non toxic and no behavioral changes, mortality was observed. On the basis of these results, the doses were selected for the study as per WHO guidelines.

Preparation and administration of dose:

Kariuppu chenduram was suspended in aqueous twin 80 solution (10%). It was administered to animals at dose levels of 1X therapeutic dose (9.36mg/animal), 5XTherapeutic dose (46.8mg/animal) and 10X Therapeutic dose (93.6mg/animal).The control animals were administered vehicle only. Administration was by oral (gavage) once a day for 30 days.

METHODOLODY:

Randomization, numbering and grouping of animal:

The animals were randomly divided into three groups for dosing up to 30 days. Each group consist of 10 animals (5 per sex in each group) were allowed acclimatization period of 7 days to laboratory conditions prior to the initiation of treatment. Each animal fur was marked with picric acid. The females were nulliparous and non pregnant.

OBSERVATION:

Experimental animals were kept under observation throughout the course of study for the following

Body weight:

Weight of each rat was recorded on day 1 and at weekly intervals throughout the course of study and at termination to calculate relative organ weights. From the data mean body weights and percent body gain were calculated.

Food and water consumption:

The quantity of food consumed by groups consisting of an animal for different doses was recorded at weekly intervals. Food consumed per animal was calculated for control and the treated dose groups

Clinical sings

All animals were observed daily for clinical sings. The time of onset intensity and duration of this symptom if any were recorded

Mortality:

All animals were observed twice daily for mortality during entire course of study.

TERMINAL STUDIES:

LABORATORY INVESTIGATIONS:

Following laboratory investigations were carried out. On day 40 animals fasted_overnight. Blood samples were collected by cardiac puncture using sodium heparin (200IU\ml) for blood chemistry and potassium EDTA (1.5 mg/ml) for hematology anticoagulant. Blood sample were centrifuged at 3000 r. p .m for 10 minutes.

Biochemical investigations:

The effect of **kariuppu chenduram** on certain biochemical parameters were examined and compared with those of the control group. The blood samples collected with heparinized bottles were centrifuged at 5000 rpm for 10 minutes to obtain clear serum for the following investigation. Glucose was estimated using commercial Glucose estimation kit (Span Diagnostics) by the method of Barham *et al.,* (1972) and Tenscher. *et al.,* (1971),Haemoglobin PCV, RBC, Erythrocyte count was estimated by Hemocytometer method of Ghai (1995). Total Leukocyte Count was estimated by Hemocytometer method of John (1972).Total, (Bilirubin test kid-malloy and evelyn 1937) direct and indirect bilirubins were determined. Alkaline phosphatase, Alanine amino tranferase (ALT) and Aspartate amino transferase (AST) were measured by using ALT and AST test kit (kind & king) .Total

protein TP concentration was determined. Albumin was determined based on its reaction with bromocresol green (binding method) .Urea was determined according to urease –berthelot method and plasma creatinine was estimated using jaffe reaction. Results of biochemical investigations conducted on day 31 revealed significant changes in the values of different parameters studied when compared with those of respective controls.

NECROPSY:

All the animals were sacrificed on day 40 under ether anesthesia. Necropsy of all animals was carried out and the weights of the organs including liver, kidneys, brain, heart, and lungs were recorded.

HISTOPATHOLOGY:

Tissue samples of organs from control and treated animals were preserved in 10% formalin for preparation of sections using microtome. The organs included liver, kidneys, heart, lungs and stomach of the animals were preserved and they were subjected to histopathological examination.

The organ pieces (3-5 micron) were fixed in 10% formalin for 24 hours and washed in running water for 24 hours .Samples were dehydrated in tissue processor and then cleaned in benzene to remove absolute alcohol. Embedding was done by passing the cleared sample through three cups containing molten paraffin at 50 degree c and then a cubical block of paraffin made by the L moulds it was followed by microtome and the slides were stained with haematoxylin–eosin stain. Stained sections of each organ were examined under light microscope at high (40X) power magnification. All the histo pathological slides were prepared at Vels university, pallavaram, Chennai.

RESULTS:

CONTROL ANIMALS

Kidney:

Shows normal renal tissue with glomeruli and tubules.

Spleen:

Shows normal spleen with lymphoid aggregation.

Liver:

Shows almost normal hepatocytes and occasional binucleate cells.

Stomach:

Shows normal mucosal glands.

Ovary:

Shows ovarian stroma with follicles and corpus leuteum.

Lung:

Shows normal alveoli.

Testis:

Shows normal tubules with spermatogenesis.

Heart:

Shows normal cardiac muscle bundles.

Brain:

Shows normal brain with nerve fibers and astrocytes.

Intestine:

Shows normal Intestinal mucosal lining with mild exudates.

Bone:

Shows normal osteocytes

Pancrea:

Shows normal acini with islets of β-cells

IMPRESSION: NORMAL STUDY

2.5MG TREATED (Low dose)

Kidney: shows normal renal tissue with glomeruli and tubules.

Spleen: shows normal spleen with lymphoid aggregation.

Liver: shows almost normal hepatocytes and occasional binucleate cells.

Stomach: shows normal mucosal glands.

Ovary: shows ovarian stroma with follicles and corpus leuteum.

Lung: shows normal alveoli.

Testis: shows normal tubules with spermatogenesis.

Heart: shows normal cardiac muscle bundles.

Brain: shows normal brain with nerve fibers and astrocytes.

Intestine: Shows normal Intestinal mucosal lining with mild exudates.

Bone: Shows normal osteocytes

Pancrea: shows normal acini with islets of β-cells

5MG TREATED (Mid dose)

Brain: shows brain with edema, microglial proliferation, shows brain with micro cystic change and astrocytic proliferation, shows brain with mononuclear infiltrate around vessel.

Kidney: shows renal tissue with focal tubular damage, interstitial inflammatory collection. Glomeruli shows epithelial proliferation.

Liver: shows hepatocytes with focal mild fatty change.

Spleen: shows congestion with lymphoid hyperplasia.

Stomach: shows near normal mucosal gland with mild exudates.

Lung: shows congested alveolar wall with mild thickening and mild emphysematous changes.

Pancreas: shows pancreas with acini and normal islets.

Testis: shows normal tubules with spermatogenesis.

Heart: shows congestion and mild inflammatory infiltration in between cardiac muscle bundles.

Ovary: shows ovarian stroma with follicles and corpus leuteum.

Intestine: Shows normal Intestinal mucosal lining with mild exudates.

Bone: Shows normal osteocytes

10MG TREATED (High dose)

Stomach: shows stomach with superficial erosion and congestion.

Heart: shows hypertrophic cardiac muscle bundles.

Spleen: shows lymphoid hyperplasia.

Brain: shows brain with edema. Astrocytes show degenerative changes.shows brain with pyknotic irregular nucleus, shows brain with vesicular nuclei and micro cystic changes.

Liver: shows marked dilatation of sinusoids, degeneration of hepatocytes, necrosis.

Kidney: shows renal tissue with tubular epithelial damage.

Pancreas: shows atrophic islet cells.

Testis: Giant cells were formed in the lumen of the seminiferous tubules and the spermatogenic cells degenerated. **Lung:** shows congestion, narrowed alveolar space and thickened alveolar wall.

Ovary: shows ovarian follicles and corpus leuteum.

Intestine: Shows normal Intestinal mucosal lining with mild exudates.

Preliminary phytochemical screening:

Qualitative phytochemical analysis of Acidic/Basic radicals and constituents in test drug - Preliminary Qualitative analysis of drug –CPM

Procedure	Observation	Inference
Test for Calcium : 2 ml of extract is taken in a clean test tube. To this add 2 ml of 4% ammonium oxide solution.	white precipitate is formed	Presence of calcium
Test for Sulphate : 2 ml of the extract is added to 5 % barium chloride solution.	Cloudy appearance present	Presence of Sulphate
Test for Chloride : The extract is treated with Silver nitrate solution	White precipitate is formed	Presence of Chloride
Test for carbonate : The substance is treated with Conc. HCl.	No effervescence is formed	Absence of carbonate
Test for Starch : The extract is added with weak iodine solution	No blue colour is formed	Absence of starch
Test for Iron (Ferric) : The extract is treated with glacial acetic acid and potassium ferrocyanide	No blue colour is formed	Absence of Ferric iron
Test for Iron (Ferrous) : The extract is treated with Conc. HNO_3 and ammonium thiocynate	Blood red colour is formed	Presence of Ferrous iron
Test for phosphate : The extract is treated with ammonium molybdate and conc. HNO_3	Yellow precipitate is formed	Presence of phosphate
Test for Tannic acid : The extract is treated with Ferric chloride	No black precipitate is formed	Absence of Tannic acid
Test for Unsaturation : 1 ml of Potassium permanganate solution is added to the extract.	Does not get decolourised	Absence of unsaturated compound
Test for saponins: Dilute extract+ 1ml of distilled water shake well.	No Froth formation	Absence of saponins
Test for sugars : **Benedict method** ; 5ml of Benedict solution heated gently then add 8 drops of diluted extract then heated in a boiling water bath.	No colour change occured	Indicates the Absence of sugar

Molisch test; Dilute extract+2 drops of Molisch+3ml conc.H_2SO_4.	No Reddish violet zones appeared	Absence of carbohydrate
Test for steroids : Liberman Burchard test ; Dilute extract +2 ml acetic anhydride+conc.H_2SO_4 .	No Formation of red colour	Absence of steroids
Test for amino acids: Dilute extract +2ml of Ninhydrin's soln .	No formation of violet colour	Absence of amino acids
Test for proteins: Biuret method ; 1ml of dilute extract+1mlof5%$CuSO_4$+ 1%NaOH.	No formation of deep blue colour	Absence of proteins
Test for Flavanoids : Dilute extract+ mg bits+2drops of conc.HCl and gently heated.	No formation of pink colour	Absence of Flavanoids
Test for phenol; Dilute extract+2drops of $FeCl_3$ soln.	No green colour is formed	Absence of phenols
Test for Tannins ; dilute extract +2ml of 10%lead acetate add.	No white precipitate formed	Absence of tannins
Test for alkaloids; Mayer's method;1ml of dilute extract + 1ml reagent. Dragendroff's method; 1ml of dilute extract+ 1ml of reagent.	 No precipitate No orange colour precipitate	Absence of alkaloids Absence of alkaloids

Table 1

Preliminary acid, basic radicals and phytochemical screening of CPM

S.No.	Constituents	CPM
1.	Calcium	present
2.	Iron (Ferric)	absent
3.	Iron (Ferrous)	present
4.	Sulphate	present
5.	Chloride	absent
6.	Carbonate	absent
7.	Starch	absent
8.	Phosphate	present
9.	Tannic acid	absent
10.	Unsaturated	absent
11.	Sugar	absent
12.	Alkaloids	absent
13.	Steroids	absent
14.	Protein	absent
15.	Tannins	absent
16.	Phenols	absent
17.	Flavanoids	absent
18.	Saponins	absent
19.	Amino acid	absent
20.	Glycosides	absent
21	Sterols	absent

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PERKIN ELMER OPTIMA 5300DV ICP-OES

SampleID	Analyte	Mean
Kariuppu Chenduram		
	As193.696	BDL
	Al 308.215	BDL
	Ca 317.933	BDL
	Cd 226.502	BDL
	Cu 324.754	BDL
	Fe 238.204	BDL
	Hg253.652	BDL
	K766.491	17.952 mg/L
	Mg 257.610	BDL
	Na 588.995	250.346mg/L
	P 214.914	16.183 mg/L
	Pb 230.204	BDL
	S 181.975	8.244 mg/L
	Si 251.611	BDL

BDL=Below detection limit

SOPHISTICATED ANALYTICAL INSTRUMENT FACILITY

IITM, CHENNAI-36

Table-1.

Colour characters of kariuppu Chenduram.

S No	Solvent used	Under ordinary light	Under ultra violet light
1	PM	**Light Brown**	**Light Brown**

PM-Powdered material

Table-2.

Physicochemical properties of kariuppu Chenduram.

S No.	Parameters	Values obtained (%w/w)	Heavy/ toxic metals	
1	Total ash value	10.35	Lead	BDL
2	Acid insoluble ash	0.56	Cadmium	BDL
3	Water soluble ash	7.16	Mercury	BDL
4	Moisture content	10.74	Arsenic	BDL

Table-3.

Colour, nature and percent yields of extracts of kariuppu Chenduram.

S.no.	Extract Solvents	Colour	Nature	% Yield(w/w)	SEM-Micro graph partical size range in micron	pH
1	Water	Light Brown	**Solid**	50	0.5 -1.5 micron	8.7 – 8.9

The following medicine was used in the study was processed by the methods prescribed in standard text books of siddha medicines.

Kariuppu chenduram) was prepared by the method prescribed in the text book of **anuboga vaithiya navaneetham.**

HR SEM-METHODOLOGY:

An SEM is essentially a high magnification microscope, which uses a focussed scanned electron beam to produce images of the sample, both top-down and, with the necessary sample preparation, cross-sections. The primary electron beam interacts with the sample in a number of key ways:-

- Primary electrons generate low energy secondary electrons, which tend to emphasize the topographic nature of the specimen.
- Primary electrons can be backscattered which produces images with a high degree of atomic number (Z) contrast.
- Ionized atoms can relax by electron shell-to-shell transitions, which lead to either X-ray emission or Auger electron ejection. The X-rays emitted are characteristic of the elements in the top few μm of the sample.

SAMPLE PREPARATION:

Sample preparation can be minimal or elaborate for SEM analysis, depending on the nature of the samples and the data required. Minimal preparation includes acquisition of a sample that will fit into the SEM chamber and some accommodation to prevent charge build-up on electrically insulating samples. Most electrically insulating samples are coated with a thin layer of conducting material, commonly carbon, gold, or some other metal or alloy. The choice of material for conductive coatings depends on the data to be acquired: carbon is most desirable if elemental analysis is a priority, while metal coatings are most effective for high resolution electron imaging applications. Alternatively, an electrically insulating sample can be examined without a conductive coating in an instrument capable of "low vacuum" operation.

The SEM is carried out by using FEI-Quanta FEG 200-High Resolution Instrument.

Resolution : 1.2 nm gold particle separation on a carbon substrate

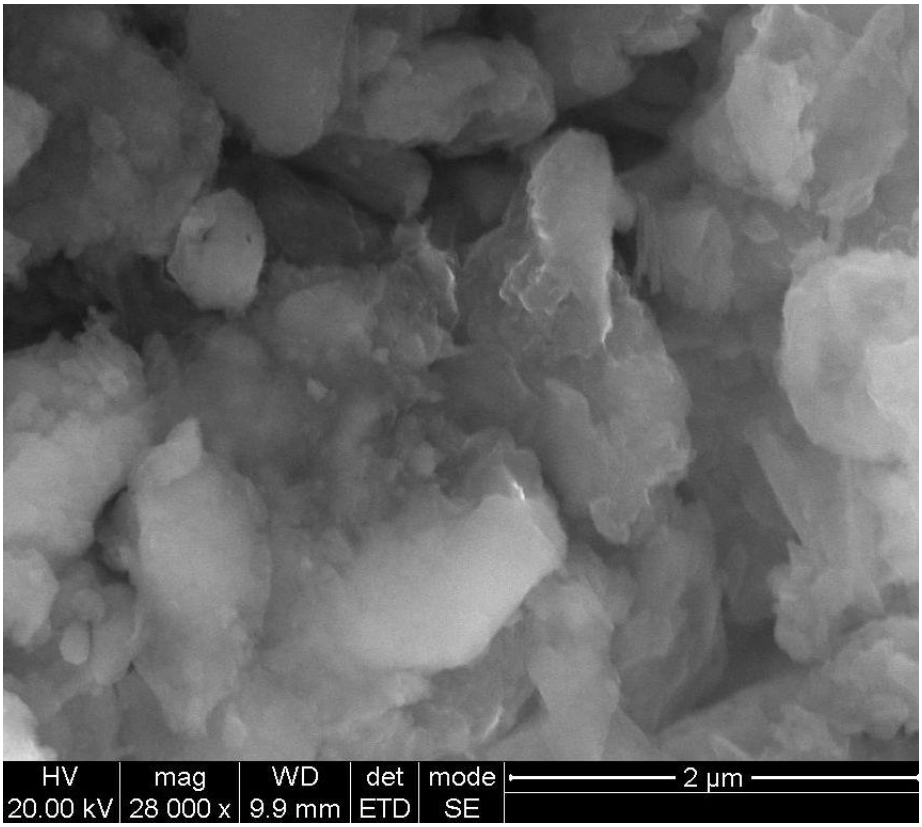
Magnification: From a min of 12x to greater than 1, 00,000 X

Application : To evaluate grain size, particle size distributions, material homogeneity and inter metallic distributions

.

Experimental Procedure: Done at SAIF, IIT Madras, Chennai-36

SEM – Micro graph partical size



NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
AYOTHIDOSS PANDITHAR HOSPITAL
DEPARTMENT OF MARUTHUVAM

PRE CLINICAL AND CLINICAL STUDY ON "CEGANAVATHAM" (CERVICAL SPONDYLOSIS) AND THE DRUG OF CHOICE IS KARIUPPU CHENDURAM (INT)&KUNTHIRIKA THAILAM(EXT)

FORM I -SCREENING & SELECTION PROFORMA

1 OP/IP NO ---------- 2 BED NO ---------- 3 SI NO----------

4 NAME ---------- 5 AGE --------- 6 GENDER --------

7 OCCUPATION ---------- 8 INCOME ----------

9 ADDRESS ---------- 10 CONTACT NO ----------

INCLUSION CRITERIA:

- Age :25-50Yrs Yes / No
- Sex : Both male and female Yes / No
- Patients with pain in nape,radiating to upper limbs with or without numbness,giddiness and neck stiffness. Yes / No
- Patients willing to take x-ray before and after treatment. Yes / No
- Patients willing to give blood sample for laboratory investigations before and after treatment. Yes / No
- Patient willing to sign the informed consent stating that he/she will conscientiously stick to the treatment during 48days. Yes / No

EXCLUSION CRITERIA:

Rheumatoid arthritis	Y/N	Pregnancy &lactation	Y/N	Use of narcotic drugs	Y/N
Renal diseases	Y/N	Diabetes mellitus	Y/N	Any other illness	Y/N
Hypertension	Y/N	Cardiac diseases	Y/N		

ADMITTED TO TRAIL: YES ☐ NO ☐ If Yes Serial No: ☐☐

Date: Station:
Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
AYOTHIDOSS PANDITHAR HOSPITAL
DEPARTMENT OF MARUTHUVAM

PRE CLINICAL AND CLINICAL STUDY ON "CEGANAVATHAM" (CERVICAL SPONDYLOSIS) AND THE DRUG OF CHOICE IS KARIUPPU CHENDURAM (INT)&KUNTHIRIKA THAILAM(EXT)

FORM I-AHISTORY PROFORMA ON ENROLLMENT

1. Serial No : _____ 2. OP/IP No:----------

3. Name: _____ 4. Gender: Female/male

5. Age (years): _____ DOB ☐☐ ☐☐ ☐☐☐☐
Date Month Year

6.Address: ----------

7.A.Occupation: ---------- B. Nature of work ----------

8. Educational Status: A) Illiterate ☐ B)Literate ☐

9.Height: cms 10.Weight: kg

11. Complaints and Duration:

_____

_____

_____

12. Habit of

A) Smoking	1. Yes; duration _____ years;	Number-		2.No
B) Alcoholism	1. Yes; duration _____ years;	Quantity-	ml	2.No
C) Tobacco chewing	1. Yes; duration _____ years			2.No
D) Betel chewing	1. Yes; duration _____ years			2.No

13.Dietry style: A.Pure vegetarian ☐ B.Non-vegetarian ☐

14. Drug History: Had the patient been treated before with allopathy drug? A) Yes ☐ B)No ☐

If Yes Name of the drugs _____, duration of treatment _____

15. MARITAL STATUS 1.Married 2.Unmarried

No of children: ☐ male: ☐ female: ☐

16. FAMILY HISTORY

Whether this problem runs in family? 1. Yes ☐ 2.No ☐

If yes, mention the relationship of affected person(s) ----------

17. MENSTURAL HISTORY:----------

18. BOWEL HABITS & MICTURITION:

Historyof habitual constipation Yes / No

History of frequent diarrhoea Yes / No

History of frequent dysuria Yes / No

19. **PSYCHOLOGICAL STATE:**

Normal ☐ Anxiety ☐ Depression ☐

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 47
AYOTHIDOSS PANDITHAR HOSPITAL
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FORM II AND II-A CLINICAL ASSESSMENT ON ENROLLMENT AND ON VISITS

1. S NO ---------- **2. OP/IP NO ---------- REG NO:32101205/2012-13**
3. NAME ---------- ---------- **4.GENDER M/F**
5. DATE OF ASSESSMENT : ----------

Initial (0th day) ☐ **12th** day ☐ 24th day ☐ 36th day ☐ 48th day ☐

SIDDHA SYSTEM OF EXAMINATION

6. ENVAGAI THERVU: [EIGHT-FOLD EXAMINATION]

I. NAADI: [PULSE PERCEPTION]

	0th day	12th day	24th day	36th Day	48th day		0th day	12th Day	24th day	36th Day	48th day
Vali						Iyyavali					
Azhal						ValiIyyam					
Iyyam						AzhalIyyam					
ValiAzhal						IyyaAzhal					
Azhalvali											

II. NAA:[TONGUE]

	0th Day	**12th Day**	**24th Day**	**36th Day**	**48th Day**
Colour	Dark / Yellow/Red / Pale/Normal	Dark/Yellow/ Red/Pale/Normal	Dark/Yellow/ Red/Pale/Normal	Dark/Yellow/ Red/Pale/Normal	Dark/Yellow Red/Pale/normal
Taste	Sweet/Bitter/Sour Pungent/None	Sweet/Bitter/Sour Pungent/None	Sweet/Bitter/Sour Pungent/None	Sweet/Bitter/Sour Pungent/None	Sweet/Bitter/Sour Pungent/None
Coating	Present/Absent	Present/Absent	Present/Absent	Present/Absent	Present/Absent
Fissure	Present/Absent	Present/Absent	Present/Absent	Present/Absent	Present/Absent
Saliva	Normal/Increased/ Decreased	Normal/Increased Decreased	Normal/Increased/ Decreased	Normal/Increased/ Decreased	Normal/Increased/ Decreased
Dryness	Present/Absent	Present/Absent	Present/Absent	Present/Absent	Present/Absent
Glossitis	Present/Absent	Present/Absent	Present/Absent	Present/Absent	Present/Absent
Baldness	Present/Absent	Present/Absent	Present/Absent	Present/Absent	Present/Absent

III.NIRAM: [COMPLEXION]

0th Day	12th day	24th Day	36th Day	48th Day
Dark/Yellow tinted/Wheatish brown / Pale	Dark/Yellow tinted / Wheatish brown/ Pale	Dark/Yellow tinted/ Wheatish brown / Pale	Dark/ Yellow tinted / Wheatish brown /Pale	Dark/ Yellow tinted/ Wheatish brown/ Pale

IV.MOZHI: [VOICE]

0th Day	12th day	24th Day	36th Day	48th Day
Medium/High Low pitched	Medium/High/ Low pitched	Medium/High/ Low pitched	Medium/High/ Low pitched	Medium/High/ Low pitched

V.VIZHI: [EYES] (Lower palpabrel conjunctiva)

0th Day	12th day	24th Day	36th Day	48th Day
Yellow Red/ Pale/Normal	Dark/Yellow Red/ Pale/Normal	Dark/Yellow Red/ Pale/Normal	Dark/Yellow Red/ Pale/Normal	Dark/Yellow Red/ Pale/Normal

VI. MALAM; [BOWEL HABITS / STOOLS]

	0th Day	12th Day	24 th Day	36th Day	48th day
Colour	Dark/ Yellow/ Pale/Others	Dark/ Yellow/ Pale	Dark/ Yellow Pale	Dark/ Yellow/ Pale	Dark/ Yellow/ Pale
Consistency	Solid/Semisolid Watery	Solid/Semisolid Watery	Solid/Semisolid Watery	Solid/Semisolid Watery	Solid/Semisolid Watery
Stool bulk	Normal/Reduced	Normal/Reduced	Normal/Reduced	Normal/Reduced	Normal/Reduced
Constipation	Present/Absent	Present/Absent	Present/Absent	Present/Absent	Present/Absent
Diarrhoea	Present/Absent	Present/Absent	Present/Absent	Present/Absent	Present/Absent

VII. URINE EXAMINATION:

NEERKURI	**0th Day**	**12th Day**	**24 th Day**	**36th Day**	**48th day**
Niram [Colour]	White/Yellowish/ Strawcoloured/ Crystal clear	White/Yellowish/ Strawcoloured Crystal clear	White/Yellowish/ Straw coloured/ Crystal clear	White/Yellowish/ Straw coloured/ Crystal clear	White/Yellowish/ Straw coloured/ Crystal clear
Manam [Odour]	Present Absent	Present Absent	Present Absent	Present Absent	Present Absent
Nurai [Froth]	Nil Reduced/Increased	Nil Reduced/Increased	Nil Reduced/Increased	Nil Reduced/Increased	Nil Reduced/Increased
Edai [Sp.gra]	Normal Increased/Reduced	Normal Increased/Reduced	Normal Increased/Reduced	Normal Increased/Reduced	Normal Increased/Reduced
Enjal [Deposits]	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent
Volume	Normal Increased/Reduced	Normal Increased/Reduced	Normal Increased/Reduced	Normal Increased/Reduced	Normal Increased/Reduced

Neikkuri					
Serpentine fashion					
Annular/Ringed fashion					
Pearl beaded fashion					
Mixed fashion					
Other fashion					

VIII. SPARISAM: [PALPATORY PERCEPTION]

0th Day	12th Day	24th Day	36th Day	48th Day
Warmth/Cold/Normal Sweat	Warmth/ Cold/Normal Sweat	Warmth/ Cold/Normal Sweat	Warmth/ Cold/Normal Sweat	Warmth/ Cold/Normal Sweat

7. THEGI: [TYPE OF BODY CONSTITUTION]

Vatham predominant		Kabam predominant	
Pitham predominant		Thondha udal	

8.NILAM: [LAND WHERE PATIENT LIVED MOST]

Kurinji ☐ Mullai ☐ Marutham ☐ Neithal ☐ Palai ☐

(Hilly terrain) (Forest range) (Plains) (Coastal belt) (Arid regions)

9. KAALAM

Kaarkalam- ☐ Pinpanikalam ☐

Koothirkalam- ☐ Ilavenil ☐

Munpanikalam - ☐ Muthuvenil ☐

10. GUNAM

Sathuvam ☐ Rasatham ☐ Thamasam ☐

11. IMPORIGAL (SENSORY ORGANS)

	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Mei (Skin)					
Vai (BuccalCavity)					
Kann (Eye)					
Sevi (Ear)					
Mooku (Nose)					

12. KANMENDRIYAM (MOTOR ORGANS)

	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Kai (upper limb)					
Kaal (lower limbs)					
Vai (buccal cavity)					
Eruvai (excretory organs)					
Karuvai (reproductive organs)					

13. KOSANGAL(Sheath)

	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
AnnamayaKosam					
Pranamayakosam					
Manomayakosam					
Vignanamayakosam					
Ananthamayakosam					

14. MUKKUTRAM:[AFFECTION OF THREE HUMORS]

A)VATHAM:

	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Praanan					
Abaanan					
Samaanan					
Udhaanan					
Viyaanan					
Naagan					
Koorman					
Kirukaran					
Devathathan					
Dhananjeyan					

B) PITHAM:

	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Analapitham					
Ranjakam					
Saathakam					
Prasakam					
Alosakam					

C) KABAM:

	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Avalambagam					
Kilethagam					
Pothagam					
Tharpagam					
Santhigam					

15. SEVEN DHATHUS: (7 SOMATIC COMPONENTS)

	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Saaram[Chyme]					
Senneer[Blood]					
Oon[Muscle]					
Kozhuppu[Fat]					
Enbu[Bones]					
Moolai[Bone marrow]					
Sukkilam/Suronitham [Genital discharges]					

16. SYSTEMIC EXAMINATION:

	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Locomotor system					
Cardio vascular system					
Respiratory system					
Gastro intestinal system					
Central nervous system					
Urogenital system					
endocrine system					

17. GENERAL EXAMINATION:

	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Height (cms)					
Weight (kg)					
Temperature(°F)					
Pulse rate (per min)					
Heart rate (per min)					
Respiratory rate(per min)					
Blood pressure(mm/Hg)					
Pallor					
Jaundice					
Cyanosis					
Lymphadenopathy					
Pedal edema					
Clubbing					
Jugular vein pulsation					

CLINICAL ASSESSMENTS:

COMPLAINTS	0^{th} day	12^{th} day	24^{th}day	36^{th} day	48^{th} day
Pain in neck					
Pain in shoulder					
Nature of pain					
Onset of pain					
Radiating pain in right upper limb					
Radiating pain in left upper limb					
Numbness					
Tenderness					
Restriction of neck movements					
Burning sensation					
Giddiness					

CLINICAL EXAMINATION

I. INSPECTION

	0^{th} day	12^{th} day	24^{th} day	36^{t} day	48^{th} day
Attitude					
Muscle wasting					
Swelling					

II PALPATION:

	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Tenderness					
Muscle spasm					
Local heat					
Local lymph Adenopathy					
Joint stiffness					

II. NECK MOVEMENTS:

	0^{th} day	12^{th} day	24^{th} day	36^{th} day	48^{th} day
Neck Stiffness					
Rotation					
Flexion					
Extension					
Lateral bending					

III. MOVEMENTS

A. HEALTH ASSESSMENT QUESTIONNAIRE:

	0th day	**12th day**	**24th day**	**36th day**	**48th day**
PAIN **A. Onset**: Sudden/Gradual					
B. Early morning Stiffness (Present/absent)					
C. Nature of pain (Mild/ Moderate/ Severe)					
D. Aggravating factor- Movement (Yes/No)					
E. Relieving factor – Rest (Yes/No)					
G. Tenderness (Present/absent)					
Restriction of neck movements(Fully/Partial/ Nil)					

Date :

Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

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FORM III LABORATORY PARAMETERS-CHART

1. OP/IP No: _____ 2.S. No: _____ 3.Reg no: 32101205/2012-13

4. Name: _____ 5. Age: _____ years 6. Gender: M/F

BLOOD INVESTIGATION		**0th DAY Date:**	**48thDay Date:**	**NORMAL VALUES**
HB (gms%)				**M:14-18 ;W:11-15**
T.RBC(milli/cu.mm)				**M:4.5-6.5 ;W:3.5-5.5**
ESR (mm)	**½ hr.**			
	1 hr.			**M:0-10 ;W:0-20**
T.WBC (cu.mm)				**4000-11,000**
DIFFERENTIAL COUNT (%)	**Polymorphs**			**40-75**
	Lymphocytes			**20-35**
	Monocytes			**2-10**
	Eosinophils			**1-6**
	Basophils			**0-1**
Blood glucose (mg/dl)	**Fasting**			**80-120**
	PP			**<130**
	Random			**<140**
Lipid profile (mg/dl)	**Serum cholesterol**			**150-250**
	HDL			**30-60**
	LDL			**Upto 130**
	VLDL			**40**
	TGL			**Upto 160**
RFT (mg/dl)	**Blood urea**			**16-50**
	Serum creatinine			**0.6-1.2**

	Serum Uric acid			**M:3-9 ;W: 2.5-7.5**
LFT (mg/dl)	**Total bilirubin**			**0.3-1**
	Direct bilirubin			**0.1-0.3**
	Indirect bilirubin			**0.2-0.8**
	Serum total protein			**6-8**
	Serum Albumin			**3.5-5.5**
	Serum globulin			**2-3.5**
	Fibrinogen(g/dl)			**0.2-0.4**
	Serum calcium			**9-11**
	Serum phosphorous			**2-5**
	SGOT (IU/L)			**6-18**
	SGPT (IU/L)			**3-26**
	Alkaline phosphatase (kingÅ units)			**3-12**

URINE INVESTIGATION	**0th DAY Date:**	**48th DAY Date:**
neikkuri		
neerkkuri		
Albumin		
Fasting sugar		
PP sugar		
Random Sugar		
Deposits		
Bile salts		
Bile pigments		
Urobilinogen		
MALAM		
Ova		
Cyst		
Occult blood		

X RAY CHANGES

X-Ray cervical spine- AP view, Lateral view

X RAY CHANGES	Before treatment (0th day)	After treatment (48th day)

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

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FORM IV-C CONSENT FORM

CERTIFICATE OF CONSENT

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care".

"I have received a copy of the information sheet/consent form".

In case of illiterate participant

"I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely."

Date:

Signature of a witness

Left thumb Impression of the Participant

(Selected by the participant bearing no connection with the survey team)

Date:

Station:

Signature of participant: Signature of the Investigator

தேசிய சித்த மருத்துவ நிறுவனம்
அயோத்திதாச பண்டிதர் மருத்துவமனை, சென்னை - 47.
பட்ட மேற்படிப்பு மருத்துவத்துறை

சகனவாதம் நோய்க்கான சித்த மருந்துகளின் (கறியுப்பு செந்தூரம் குந்திரிக்க தைலம்) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான ஒப்புதல் படிவம்

FORM IV- C ஒப்புதல் படிவம்

நான் மேற்கூறிய தகவல் படிவத்தை படித்து அல்லது படிக்க கேட்டு கொண்டேன். - து தொடர்பான விளக்கங்களையும் கேட்டு தெரிந்து கொண்டேன்.எந்த வித வற்புறுத்தலின்றி, என் சொந்த விருப்பத்தின் பேரில் என்னை - ந்த ஆராய்ச்சிக்கு உட்படுத்த என் முழுமனதோடும் சுயநினைவோடும் சம்மதம் தெரிவிக்கிறேன்.எனக்கு விருப்பமில்லாத பட்சத்தில் இந்த ஆராய்ச்சியில் இருந்து என்னை எப்போதுவேண்டுமானாலும் விடுவித்து கொள்ளும் உரிமையை பெற்றுள்ளேன் என்பதையும் அறிவேன்.

தேதி: கையொப்பம்:

இடம்: பெயர் :

தேதி: சாட்சிக்காரர் கையொப்பம்:

இடம்: பெயர் :

உறவுமுறை :

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FORM IV -E (WITHDRAWAL FORM)

S. NO: ---------- **OPD/ IPD NO: --------** **REG NO: 32101205/2012-13**

NAME: ---------- **AGE: --------** **GENDER: M/F**

DATE OF TRIAL COMMENCEMENT: ----------

DATE OF WITHDRAWAL FROM TRIAL: ----------

REASONS FOR WITHDRAWAL:

- Long absence at reporting : Yes/ No
- Irregular treatment: Yes/ No
- Shift of locality : Yes/No
- Increase in severity of symptoms: Yes/No
- Development of severe adverse drug reactions: Yes/No

Date :

Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

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FORM IV A (DRUG COMPLIANCE FORM)

S. NO: OPD/IPD NO : NAME : REG NO: 32101205/2012-13
Name Of The Drug :KARIUPPU CHENDURAM (Internal)KUNTHIRIKA THYLUM(External)
Dose:260 mg with honey[int}
Drugs issued: Drugs issued:
Drugs returned: Drugs returned:

S.NO	DATE	DRUG TAKEN TIME	
		MORNING After food	EVENING After food
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			
Day 8			
Day 9			
Day 10			
Day 11			
Day 12			

Date :
Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

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FORM IV A (DRUG COMPLIANCE FORM)

S. NO: OPD/IPD NO : NAME : REG NO: 32101205/2012-13

Name Of The Drug :KARIUPPU CHENDURAM (Internal)KUNTHIRIKA THYLUM(External)

Dose:260 mg with honey[int}

Drugs issued: Drugs issued:

Drugs returned: Drugs returned:

DAYS	DATE	DRUG TAKEN TIME	
		MORNING After food	EVENING After food
Day 13			
Day 14			
Day 15			
Day 16			
Day 17			
Day 18			
Day 19			
Day 20			
Day 21			
Day 22			
Day 23			
Day 24			

Date :

Station:

Signature of the Investigator:

Signature of the Lecturer: Signature of the HOD

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FORM IV A (DRUG COMPLIANCE FORM)

S. NO: OPD/IPD NO : NAME : REG NO: 32101205/2012-13
Name Of The Drug :
Dose:260 mg with honey[int}
Drugs issued: Drugs issued:
Drugs returned: Drugs returned:

S.NO	DATE	DRUG TAKEN TIME	
		MORNING	EVENING
Day 25			
Day 26			
Day 27			
Day 28			
Day 29			
Day 30			
Day 31			
Day 32			
Day 33			
Day 34			
Day 35			
Day 36			

Date :
Station:
Signature of the Investigato
Signature of the Lecturer:

Signature of the HOD

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FORM IV A (DRUG COMPLIANCE FORM)

S. NO: OPD/IPD NO : NAME : REG NO: 32101205/2012-13
Name Of The Drug :KARIUPPU CHENDURAM (Internal)KUNTHIRIKA THYLUM(External)
Dose:260 mg with honey[int}
Drugs issued: Drugs issued:
Drugs returned: Drugs returned:

DAYS	DATE	DRUG TAKEN TIME	
		MORNING	EVENING
Day 37			
Day 38			
Day 39			
Day 40			
Day 41			
Day 42			
Day 43			
Day 44			
Day 45			
Day 46			
Day 47			
Day 48			

Date :
Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

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FORM IV F

ADVERSE REACTION FORM

Reg No:32101205/2012-13

Serial No: OP/IP No:

Name: Age: Gender: M/F

Date of trial commencement:

Date of the adverse reaction occur;

Time: Description of Adverse reaction:

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD

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அயோத்திதாச பண்டிதர் மருத்துவமனை, சென்னை - 47.
பட்ட மேற்படிப்பு மருத்துவத்துறை

சகனவாதம் நோய்க்கான சித்த மருந்துகளின் (கறியுப்பு செந்தூரம் குந்திரிக்க தைலம்) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான ஒப்புதல் படிவம்

FORM IV- D உணவு அறிவுரை படிவம்

- **காய்கள்**

  கத்தரிபிஞ்சு,முருங்கைபிஞ்சு,,அவரைபிஞ்சு,
  ஆகியவை சேர்க்க வேண்டும்.

- **கீரைகள்**:

  பொன்னாங்கண்ணி,மூக்கிரட்டை,தூதுவேளை,

  முருங்கைகீரை,கறிவேப்பிலை, முடக்கறுத்தான் அறுகீரை கரிசாலை ஆகியவை சேர்க்க வேண்டும்.

- **பழங்கள்**:

  மாதுளை,ஆப்பிள், பப்பாளி, ஆரஞ்சு, பேரீச்சை, அத்தி,
  நாவல் ,ஆகியவை சேர்க்க வேண்டும்.

- **அசைவம்**:

  வெள்ளாட்டுகறி, காடை, சிறு இறால் மீனை கத்திரிக்காய்,
  அவரைக்காய்,முதலியபொரியல்களோடு கூட்டிச்
  செய்துதரலாம்.
  துவரம்பருப்புரசம், சேர்க்க வேண்டும்.

- ஈரமில்லா தரையிலும், படுக்கையிலும் படுத்தல் வேண்டும்
- குளிர்காற்று படும்படியானடத்திலிருப்பதை தவிர்க்கவும்
- தலை மற்றும் கையில் கனமான பொருள்கள் தூக்க கூடாது
- தலைக்கு தலையணை வைத்து தூங்க கூடாது

சேர்க்க கூடாதவைகள்:

• சுரை	உப்பு
• பூசணி	புளிப்பு
• வெள்ளரிக்காய்	அதிக கைப்பு
• புடலை	அதிக கார்ப்பு
• பீர்க்கு	மந்தப் பொருள்
• மொச்சை	வெற்றிலை,பாக்கு
• காராமணி	புகையிலை
• உளுந்து	மது அருந்துதல்
• கொள்ளு	

AYOTHIDOSS PANDITHAR HOSPITAL
DEPARTMENT OF MARUTHUVAM
PRE CLINICAL AND CLINICAL STUDY ON CEGANAVATHAM (cervical spondylosis)
KARIUPPU CHENDURAM (Internal),
KUNTHIRIKA THYLAM(External)
FORM IV –B (INFORMATION SHEET)

Name of Principal Investigator:……..……..

Part – A Information Sheet

I, Dr.M.S.SARANYA DEVI studying M.D(S) in National Institute of Siddha, Chennai. CEGANAVATHAM is a disease affecting the morbidity and causing discomfort to the person. This condition is being treated in NIS with many Siddha formulations. As a part of M.D(S) research programme and developing new efficacious medicine, we propose to study the **KARIUPPU CHENDURAM (Internal), KUNTHIRIKA THYAM(External)** formulations for treating the condition. This formulation has been mentioned in Siddha literature and empirical evidence with contemporary tools is required for documentation. You can receive medicines free of cost. The duration of treatment period is 48 days. You have to visit NIS once in every 12 days and collect the drugs for 12 days. The diagnosis tests will be carried out at free of cost. We will assess the effect of treatment after completions of days of treatment using clinical and laboratory parameters.

In this regard, we need to ask few questions. We will maintain confidentiality of your comments and data obtained from you. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study.

Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study. You can choose not to answer any specific question. There is no specific benefit for you if you take part of in this study, but you will be under our clinical monitoring and specific attention will be given for your help. Taking part in this study may be of benefit to the community, as it may help us to develop medicine for Cegana Vaatham. In case of any adverse symptoms during the treatment passing loosey stools,irritation in the stomach , indigestion which is expected for few patients during the treatment, shall be reported to PIs and care will be taken in NIS for relief. You can withdraw from the study at the midst of treatment period, if you are not interested to continue and you will receive our usual treatment without condition.

The information we will be collected in the study, will remain between you and the principal investigator. We will ask you a few questions through a questionnaire. We will not write your name on different forms which send to different investigating / analysis sections and we will use a code instead given by principal investigator. Only the principal investigator will know the key to this code which will be kept in safe custody. If you agree to be the participant in this study, you will be screened as per the study protocol.

If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact, Dr.M.S.SARANYA DEVI P.G scholar cum principal investigator of this study, attached to the National Institute of Siddha, Chennai(Mobile No. 9698041421). You can also contact the chairman / Member Secretary of ethics committee, National Institute of Siddha, Chennai-600047, Tel No.: 914422411611, for rights and participation in the study.

தேசிய சித்த மருத்துவ நிறுவனம், சென்னை 47

அயோத்திதாசர் பண்டிதர் மருத்துவமனை

சகனவாதம் நோய்க்கான சித்த மருந்தின் கறியுப்பு செந்தூரம்,குந்திரிக்க தைலம் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

FORM IV தகவல் படிவம்

முதன்மை ஆராய்ச்சியாளர் பெயர் : Dr.**ம.ச.சரண்யா தேவி**

நிறுவனத்தின் பெயர் : தேசிய சித்த மருத்துவ நிறுவனம்

தாம்பரம் சானடோரியம்

சென்னை- 47

Dr. ம.ச.சரண்யா தேவி ஆகிய நான் தேசிய சித்த மருத்துவமனையில் பட்ட மேற்படிப்பு பயின்று வருகிறேன்.

சகனவாதம் என்னும் நோயானது கழுத்து எலும்பை பாதிக்கும் நோயாகும். இந்நோயானது கழுத்து, தோள்பட்டை, கை முதலிய இடங்களில் வலி, நீட்டி மடக்க முடியாமை, ஆகிய குறிகுணங்கள் காணும். இந்நோய்க்கு தேசிய சித்த மருத்துவமனையில் பல சித்த மருந்துகள் பயன்படுத்தப்பட்டு வருகின்றது. சித்த மருத்துவ பட்ட மேற்படிப்பில், ஆய்வின் ஒரு பகுதியாக புதிய மருந்துகளை பயன்படுத்தும் நோக்கில் இந்நோய்க்கு கறியுப்பு செந்தூரம், ,குந்திரிக்க தைலம் வழங்க பரிந்துரை செய்கிறோம். இந்த மருந்தின் செய்முறை, அளவு, அனுபானம் மற்றும் மருத்துவ பயன்கள் அனைத்தும் அங்கீகரிக்கப்பட்ட சித்த மருத்துவ நூலில் கூறப்பட்டுள்ளது. எந்தவித கட்டணமுமின்றி தாங்கள் இந்த மருந்தினை பெற்றுக்கொள்ளலாம். இந்த ஆய்வில் மருந்து உட்கொள்ளும் காலம் 48 நாட்கள் ஆகும். வெளி மருந்தாக 50 மிலி 48 நாட்களுக்கு நோயுள்ள இடங்களில் வெளியே தடவ வேண்டும். வெளி நோயாளர்கள் 12 நாட்களுக்கு ஒரு முறை மருத்துவமனைக்கு வரவேண்டும். 48 நாட்கள் மருந்து உட்கொள்ளும் காலம் முடிந்த பிறகு நோய்க்கான குறிகுணங்கள் மற்றும் ஆய்வக பரிசோதனைகள் இவற்றின் முடிவுகளின் அடிப்படையில் மருந்தின் பரிகரிப்புத்திறன் கண்டறியப்படும். இந்த ஆய்வு சம்பந்தமாக சில கேள்விகளை தங்களிடம் கேட்க இருக்கிறேன். தங்களிடமிருந்து பெறப்படும் கருத்துக்கள் மற்றும் குறிப்புகள் அனைத்தும் நம்பிக்கையாக பதிவு செய்யப்படும்.இந்த ஆய்வில் தங்களை உட்படுத்திக்கொள்வதின் மூலம் எந்த வகையிலும் பாதிப்புக்குள்ளாகமாட்டீர்கள் என உறுதி அளிக்கிறேன்.

எந்தவித வற்புறுத்தலுமின்றி, இந்த ஆய்வில் பங்கேற்கவும், இந்த ஆய்வு சம்பந்தமாக கேட்கப்படும் கேள்விகளுக்கு பதில் கூறவும் தங்களுக்கு முழு சுதந்திரம் அளிக்கப்படுகிறது. இந்த ஆய்வில் பங்கேற்பதற்கு எந்த சன்மானமும் வழங்கப்படமாட்டாது. ஆனால், ஆய்வு முழுவதும் எனது மேற்பார்வையிலும், தங்கள் உடல்நலன் குறித்த தனி கவனத்திலும் ஆய்வு மேற்கொள்ளப்படும். கும்பவாத நோய்க்கான புதிய மருந்தின் பரிகரிப்புத்திறனை சமூகத்திற்கு உணர்த்தும் வகையில் இந்த ஆய்வு மேற்கொள்ளப்படுகிறது, இந்த ஆய்வில், மருந்து உட்கொள்ளும் காலத்தில் வயிற்றுவலி, அடிக்கடி மலம் கழிதல், உண்ட உணவு செரியாமை,போன்ற மாறுபட்ட குறிகுணங்கள் தொடர்ந்து இருக்கும் பட்சத்தில், முதன்மை ஆராய்ச்சியாளரான என்னிடம் தெரிவிக்கப்பட்டு, தேசிய சித்த மருத்துவமனையில் அதற்க்கான தீர்வு வழங்கப்படும். இந்த ஆய்வினைத் தொடர தங்களுக்கு விருப்பம் இல்லையெனில், எப்பொழுது வேண்டுமானலும் ஆய்வின் இடையில் விலகிக்கொள்ளவும், மருத்துவமனையில் வழங்கப்படும் இந்நோய்க்கான வழக்கமான மருந்துகளை பெற்றுக்கொள்ளவும் அறிவுறுத்தப்படுகிறீர்கள்.

இந்த ஆய்வில் சேகரிக்கப்படும் விபரங்கள் அனைத்தும் தங்களுக்கும் முதன்மை ஆராய்ச்சியாளரான எனக்கும் இடையில் இரகசியமாக வைக்கப்படும். கேள்வி பதில் வடிவத்தில் தங்களிடம் கேள்விகள் கேட்கப்படும். அனைத்துப் படிவங்களிலும் தங்களின் பெயர் தவிர்க்கப்பட்டு ஆய்வாளரால் தங்களுக்கென தனிக் குறியீடு வழங்கப்படும். அந்தக் குறியீடு ஆய்வாளருக்கு மட்டுமே தெரிந்ததாக இருக்கும். நீங்கள் இந்த ஆய்வில் பங்கேற்க விருப்பப்பட்டால், முன்னோட்ட ஆய்வு தகவல் படி தேர்வு செய்யப்படுவீர்கள்.

நீங்கள் இந்த ஆய்வில் பங்கேற்கும் முன், இந்த ஆய்வினைப் பற்றிய மேலும் விபரங்கள் பெற வேண்டுமென விருப்பப்பட்டால், இந்த ஆய்வின் முதன்மை ஆராய்ச்சியாளர் மற்றும் தேசிய சித்த மருத்துவமனை, பட்ட மேற்படிப்புத்துறை மாணவர் Dr ம.ச.சரண்யா தேவி.ஆகிய என்னை 9698041421 என்ற எண்ணில் தொடர்பு கொள்ளலாம். மேலும், நீங்கள் இந்த ஆய்வில், உங்களது பங்கேற்பு மற்றும் உரிமை பற்றி தெரிந்து கொள்ள தேசிய சித்த மருத்துவமனை, தலைவர்/செயற்க்குழு உறுப்பினர் அவர்களையும் 91-44-22411611 என்ற எண்ணில் தொடர்பு கொள்ளலாம்.

ANNEXURE – V

CERTIFICATES

NATIONAL INSTITUTE OF SIDDHA
(An Autonomous Body under Department of AYUSH)
Ministry Of Health & Family Welfare, Government of India

Tambaram Sanatorium, Chennai - 600 047
Tel : 044-22411611 Fax : 044-22381314
E-mail : nischennaisiddha@yahoo.co.in
Website : www.nischennai.org

Name: Dr.M.S.SARANYA DEVI, REG NO: 32101205
Title: Preclinical and clincal study On Ceganavatham (Cervical Spondylosis) & the drug of choice is Kariuppu Chenduram (Int) and Kunthirika thailam (External)
No. NIS/IEC/2011/3/05 - 24/12/2011

DECSION

Opinion of the Institutional Ethics Committee – Please Check one
✓ Approval _____ Modifications required prior to approval (Please specify one space below) _____ Disapproval Date of review: _____ K. Thamizhalagan (Dr.K.MANICKAVASAKAM) Member Secretary Signed: _____ (Please print name) Dr.V.SUBRAMANIAN Chair Person (Please delee as appropriate, Chairperson, Secretary)
Modifications needed Modification given to candidate
The research proponent is hereby informed that the Institutional Ethics Committee will require the following: 1. All adverse drug reactions (ADRs) that are both serious and unexpected to be reported promptly to the IEC within 7 working days 2. The progress report to be submitted to the IEC atleast annually 3. Upon completion of the study, a final study status report needs to submitted to the IEC

IAEC PROTOCOL NO: 1248/ac/09/CPCSEA/4-05/2011

20/12/2011

CERTIFICATE

This is certify that the project title.. Preclinical and clinical study on Gridhranavathan (Cervical Spondylosis) & the drug of choice is "Kanuppu Chendooram" **has been approved by the IAEC.**

Prof. Dr. K. Manickavasakam
Name of Chairman/Member Secretary IAEC:

Dr. B. Jayachandran Dare
Name of CPCSEA nominee:

Signature with date

Chairman/Member Secretary of IAEC:

CPCSEA nominee:

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by Office)

சித்த மருத்துவ மைய ஆராய்ச்சி நிலையம், அரும்பாக்கம், சென்னை - 600 106
सिध्द केन्द्रीय अनुसंधान संस्थान, अरुम्बाक्कम, चेन्नई- 600106
Siddha Central Research Institute
Arignar Anna Govt. Hospital Campus, Arumbakkam, Chennai-600 106
(Central Council for Research in Siddha, Department of AYUSH,
Ministry of Health & Family Welfare, Govt. of India)
Phone: 044-2621 49 25,
Tele Fax: 044 26214809,
E.mail: cnsiddha@gmail.com
Web: www.cnsiddha.tn.nic.in

06.02.2012

CERTIFICATE

Certified that the mineral submitted for identification by Dr.M.S.Saranyadevi, II year Maruthuvam, National Institute of Siddha, Tambaram Sanatorium, Chennai-47 is identified as Kariuppu – Sodium Chloride.

(R.Shakila)
Research Officer (Chemistry)

(K.Meenakshi Sundara Moorthy)
Asst. Director- In charge

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

CERTIFICATE OF BOTANICAL AUTHENTICITY

Certified that the following plant drugs used in the Siddha formulation **Kariuppu Chenduram** (Internal) and **Kunthirika Thailam** (External) for the treatment of **Cegana vatham** (Cervical spondylosis) taken up for Post Graduation Dissertation studies by **Dr.M.S.Saranya Devi**, M.D.(S), II year Department of Maruthuvam, 2011-12, are identified and authenticated through Visual inspection / Experience, Education & Training/ Organoleptic characters/ Morphology / Micromorphology / Taxonomical/ Microscopical methods.

Calotropis gigantea Linn. (Asclepiadaceae), Leaf
Sesamum indicum Linn. (Pedaliaceae), Seed oil
Pistacia lentiscus Linn. (Anacardiaceae), Resin

Certificate No: NIS/MB/41/2012

Date: 12-03-12

12/3/12
Authorized Signatory
Dr. D. ARAVIND, M.D.(s),M.Sc.,
Assistant Professor
Department of Medicinal Botany
National Institute of Siddha
Chennai - 600 047, INDIA

SOPHISTICATED ANALYTICAL INSTRUMENT FACILITY
INDIAN INSTITUTE OF TECHNOLOGY, MADRAS
Chennai - 600 036. INDIA

CERTIFICATE

Certified that mineral drug **KARIUPPU CHENDURAM** formulated by **Dr.M.S.SARANYA DEVI** III Year M.D(S) Department of Maruthuvam, National Institute of Siddha , Tambaram Sanatorium was analysed (quantitative) by ICP-OES, HR-SEM and Physico chemical Analysis Methods at SAIF, IITM, Chennai-600 036, during October 2012.

Dr. R. MURUGESAN
Scientific Officer Gr.-I
Sophisticated Analytical Instrument Facility
Indian Institute of Technology, Madras
Chennai-600 036

Phone : 91-44-2257 4935 Fax : 91-44-2257 0545, 2257 0509
e-mail : saif@iitm.ac.in http://www.saif.iitm.ac.in

The Tamil Nadu Dr. M.G.R. Medical University

69, Anna Salai, Guindy, Chennai-600 032

This Certificate is awarded to ~~Mr/Ms~~/Dr.....M.S. SARANYADEVI.....

for participating as a ~~Resource Person~~ / Delegate in the VII Workshop

on **"Research Methodology & Biostatistics"**

for AYUSH Post-Graduates & Researchers

organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University

from 6th Feb. 2012 to 10th Feb. 2012.

DR. MAYILVAHANAN NATARAJAN
M.S.Orth. M.Ch.Orth. (L'pool) Ph.D. (Orth. Onco.) F.R.C.S. (Eng) D.Sc.
7th VICE CHANCELLOR

Dr. R. SRILAKSHMI, DCH, Ph.D.
REGISTRAR

Dr. N. KABILAN, M.D. (Siddha)
READER, DEPT. OF SIDDHA

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LAB INVESTIGATION BEFORE AND AFTER TREATMENT

SL. NO	OP/IP NO	AGE/SEX	Hbgm%		TRBC Million cells /cumm	
			Before treatment	After treatment	Before treatment	After treatment
1	C95550	31/F	15.2	14	4.4	4.9
2	D00464	40/F	18.1	18	5	5
3	C95513	40/F	16.5	16	5.5	5.3
4	C94392	31/F	14.8	15	5.5	5.5
5	D004308	45/F	14	14.5	4.4	4.5
6	C098191	40/F	13	13	4	4.1
7	C098214	40/F	14.5	14.6	5.2	5.3
8	C96651	50/F	17.4	17	4.8	5.2
9	C97647	30/F	11	12	4.5	4.3
10	D000836	25/F	13	13.5	4.9	4.9
11	C099666	37/F	14.1	14.5	6	6.2
12	C97598	48/F	10	10.5	5	5.1
13	C098014	32/F	12.9	12.5	3.9	4.9
14	C099250	47/F	9.7	10	4.8	4.4
15	C95436	44/F	8	9	4.5	4.5
16	D000496	38/F	11.5	12.1	5.5	5.2
17	C098239	38/F	12.4	12	5.5	5.5
18	C97940	48/F	14.4	14.2	4.1	4.2
19	C94733	32/F	12.6	12.4	5.1	5.1
20	D000006	32/F	12.6	12.6	5.5	5.7
21	D000425	37/M	11	11.5	5.5	5.6
22	D000205	48/M	12.5	12	4.5	4.7
23	B55586	26/M	11.5	12	4.9	5.2
24	C96984	50/M	11	11	5.5	5.2
25	D004970	47/M	14	14	4.9	4.7
26	C94873	29/M	11.8	12	4.8	5
27	C93620	38/M	13.2	13	5.8	5.4
28	C94833	26/F	12	11.8	5.4	4.9
29	C96489	31/F	13.9	14	4.7	4.5
30	C96802	25/F	11	11	5.6	5.7
31	4185	48/F	10	10.5	4.8	4.9
32	4228	32/F	10.5	10.5	5.4	5.6
33	4258	37/F	11	11	4	4
34	4267	42/F	11.5	11.5	5.8	5.9
35	4251	48/F	12	12	4.9	4.6
36	4255	40/F	12.1	11	4.3	4.1
37	4175	42/F	12.8	13	4.1	4
38	4226	34/F	11.1	11.2	4.3	4.4
39	4209	42/F	10	11	3.6	3.9
40	5217	26/M	13.5	13	4.4	4.9

LAB INVESTIGATION BEFORE TREATMENT

Sno	OP/IP No	Age/Sex	T.Billirubin mg/dl	D.Billirubin mg/dl	ID.billirubin mg/dl	SGOT U/l	SGPT U/l	SAP U/l	T.Protein Gm/dl	Albumin gm/dl	Globulin gm/dl	Calcium mg/dl	Phosphorous mg/dl
1	C95550	31/F	0.5	0.3	0.2	20	22	131	6.8	5.4	1.4	11.8	3.3
2	D00464	40/F	0.9	0.5	0.4	24	25	115	7.2	5.3	1.9	13.3	2.9
3	C95513	40/F	0.5	0.3	0.2	18	26	127	7.9	5.8	2.1	12.4	5.1
4	C94392	31/F	0.5	0.3	0.2	22	21	230	7.4	5.4	2	10.6	5.9
5	D004308	45/F	0.4	0.2	0.2	19	21	121	7.6	5.5	2.1	11.6	4.2
6	C098191	40/F	0.7	0.4	0.3	17	16	185	6.9	5.4	1.5	11.5	3.6
7	C098214	40/F	0.5	0.3	0.2	25	27	170	6.9	5.4	1.5	11.9	2.6
8	C96651	50/F	0.5	0.3	0.2	21	28	200	6.7	4.8	1.9	11.7	2.8
9	C97647	30/F	0.7	0.4	0.3	20	22	240	7.7	5.1	2.6	12	3
10	D000836	25/F	0.6	0.2	0.4	17	19	202	7.5	4.4	3.1	13.4	3
11	C099666	37/F	0.6	0.3	0.3	22	25	146	7.9	5	2.9	11	3.9
12	C97598	48/F	0.6	0.3	0.3	20	22	128	7	5.1	1.9	12.1	2.3
13	C098014	32/F	0.7	0.3	0.4	23	25	218	7	4.9	2.1	9.6	2.5
14	C099250	47/F	0.6	0.2	0.4	20	21	129	7.6	4.1	3.5	9.1	3.2
15	C95436	44/F	0.6	0.4	0.2	13	15	138	6.5	4.3	2.2	10	2.3
16	D000496	38/F	0.6	0.2	0.4	18	20	269	6.9	4.3	2.6	11	3.7
17	C098239	38/F	0.6	0.2	0.4	20	24	221	7.5	5.1	2.4	11.2	3.3
18	C97940	48/F	0.6	0.2	0.4	24	26	185	6.2	4	2.2	10.2	3.9
19	C94733	32/F	0.8	0.3	0.5	23	28	166	7.1	4.5	2.6	11.2	4.4
20	D000006	32/F	1.2	0.6	0.6	22	21	129	6.8	4.5	2.3	10.8	4
21	D000425	37/M	0.6	0.2	0.4	27	23	157	6.9	4.6	2.2	10.9	3.1
22	D000205	48/M	0.5	0.2	0.3	16	18	184	7.1	5	2.1	10.3	2.8
23	B55586	26/M	0.5	0.2	0.3	24	22	260	7	4	3	9.8	3.1
24	C96984	50/M	0.9	0.4	0.5	15	16	186	7.1	4.5	2.6	10.1	3
25	D004970	47/M	0.6	0.2	0.4	21	22	238	7.7	4.8	2.9	10.6	3.1
26	C94873	29/M	0.5	0.2	0.3	16	18	170	7.6	5.6	2	9	3.8
27	C93620	38/M	1	0.6	0.4	25	24	165	7.9	4.7	3.2	11.3	3.6
28	C94833	26/F	0.4	0.2	0.2	24	25	200	7	5	2	10.4	3.6
29	C96489	31/F	0.4	0.2	0.2	24	26	180	7	4	3	10	2.9
30	C96802	25/F	0.5	0.2	0.3	25	23	220	7.1	3	4.1	10.7	2.8
31	4185	48/F	0.6	0.2	0.4	17	19	149	6.2	4	2.2	10.4	3
32	4228	32/F	0.5	0.2	0.3	14	15	187	6.9	3.4	3.5	11.4	2.8
33	4258	37/F	0.6	0.2	0.4	15	17	220	5	3	2	10.8	3
34	4267	42/F	0.4	0.2	0.2	24	21	256	7	4.3	2.7	12.8	2.8
35	4251	48/F	0.8	0.3	0.5	18	20	145	7.8	4.6	3.2	10.4	3
36	4255	40/F	0.4	0.2	0.2	21	22	170	6.6	4.5	2.1	10.6	3.1
37	4175	42/F	1	0.6	0.4	12	10	136	6.6	4.5	2.1	10	3
38	4226	34/F	0.5	0.2	0.3	20	22	159	6.4	4.2	2.2	10.5	3
39	4209	42/F	0.6	0.2	0.4	21	23	168	6.8	4.8	2	12.4	2.8
40	5217	26/M	1	0.5	0.5	20	21	166	6.5	4	2.5	10.9	2.9

LAB INVESTIGATION AFTER TREATMENT

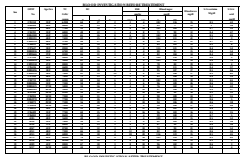
Sno	OP/IP No	Age/Sex	T.Billirubin mg/dl	D.Billirubin mg/dl	ID.billirubin mg/dl	SGOT U/l	SGPT U/l	SAP U/l	T.Protein gm/dl	Albumin gm/dl	Globulin gm/dl	Calcium mg/dl	Phosphorous mg/dl
1	C95550	31/F	0.6	0.2	0.4	18	19	190	7	5.2	1.8	11	3
2	D00464	40/F	0.7	0.2	0.5	21	26	216	6	4	2	11.3	2.7
3	C95513	40/F	1.1	0.5	0.6	19	28	119	6.1	3.2	2.9	11	3
4	C94392	31/F	0.4	0.2	0.2	24	24	262	6.8	4	2.8	10.1	4.6
5	D004308	45/F	0.5	0.2	0.3	15	16	121	7	5	2	11	3
6	C098191	40/F	0.4	0.2	0.2	21	28	190	6.9	3.9	3	10	3
7	C098214	40/F	0.3	0.2	0.1	16	17	195	7.4	4.4	3	10.6	2.8
8	C96651	50/F	0.6	0.2	0.4	21	24	211	6.5	4.5	2	11	3.6
9	C97647	30/F	0.5	0.2	0.3	19	20	152	7.7	5.7	2	12.2	3.6
10	D000836	25/F	0.5	0.2	0.3	23	26	236	6.4	3.4	3	12.2	2.8
11	C099666	37/F	0.7	0.3	0.4	16	20	186	7.5	5.5	2	10.5	3
12	C97598	48/F	0.5	0.2	0.3	22	27	196	7.5	5.5	2	9.3	2
13	C098014	32/F	0.6	0.2	0.4	24	23	213	6.7	4.2	2.5	11	3.2
14	C099250	47/F	0.5	0.2	0.3	12	14	147	6.6	4.1	2.5	10.1	3
15	C95436	44/F	0.4	0.2	0.2	11	12	145	6	3.6	2.4	9.8	2
16	D000496	38/F	1.1	0.5	0.6	19	25	176	6.6	3.7	2.9	10.8	3.1
17	C098239	38/F	0.4	0.2	0.2	11	23	177	6	3.6	2.4	9.9	2.7
18	C97940	48/F	0.5	0.2	0.3	16	26	186	6.6	4.1	2.4	10.1	3.5
19	C94733	32/F	0.5	0.2	0.3	16	17	183	5.6	3.1	2.5	10.8	3.5
20	D000006	32/F	1	0.5	0.5	18	22	220	6.2	4.2	2	9.2	3.8
21	D000425	37/M	0.7	0.3	0.4	23	26	176	6	4	2	9.8	2.8
22	D000205	48/M	0.7	0.3	0.4	19	20	156	6.4	4.4	2	9.6	2.6
23	B55586	26/M	0.6	0.2	0.4	23	25	170	6.9	4.3	2.6	10.1	3
24	C96984	50/M	1	0.7	0.3	22	27	166	6.5	4.4	2.1	10.8	3
25	D004970	47/M	0.5	0.2	0.3	22	24	198	6.2	4	2.2	10.8	2.9
26	C94873	29/M	0.5	0.2	0.3	24	26	179	6.5	4.5	2	11	3.2
27	C93620	38/M	1	0.5	0.5	23	26	168	5.9	2.6	3.3	10.2	2.9
28	C94833	26/F	0.9	0.3	0.6	16	18	144	5	3	2	10	2.9
29	C96489	31/F	0.5	0.2	0.3	19	21	149	6.6	3.6	3	10.4	2.9
30	C96802	25/F	0.8	0.3	0.5	24	26	242	6.6	4.4	2.2	11.1	3.3
31	4185	48/F	0.6	0.2	0.4	16	14	135	6	4	2	9.6	2.3
32	4228	32/F	0.4	0.2	0.2	13	15	164	6.2	4.2	2	10.2	2.5
33	4258	37/F	0.6	0.2	0.4	13	14	135	5.9	4.5	1.4	9.7	2.9
34	4267	42/F	0.4	0.2	0.2	23	21	220	6.4	4.4	4	10.2	2.4
35	4251	48/F	0.8	0.3	0.5	18	20	145	7.8	4.6	3.2	10	3
36	4255	40/F	1.2	0.6	0.6	16	17	161	7	5	2	10.4	2.9
37	4175	42/F	3.6	1.2	2.4	12	14	150	6.5	4.1	2.4	10.2	2.9
38	4226	34/F	0.5	0.2	0.3	18	16	154	6.2	4.2	2	9.6	2.8
39	4209	42/F	0.5	0.2	0.3	11	12	140	6	3	2	10.8	3.3
40	5217	26/M	0.8	0.4	0.4	18	17	160	6.4	4	2.4	9.8	2.5

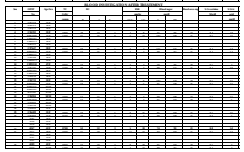
LAB INVESTIGATION BEFORE AND AFTER TREATMENT

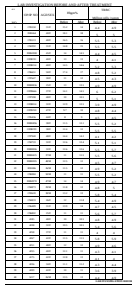
S.NO	OP/IP NO	Age/sex	T.CHOLESTEROL mg/dl		HDL mg/dl		LDL mg/dl		VLDL mg/dl		TGL mg/dl	
			BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	C95550	31/F	151	151	37	30	93	102	21	25	103	126
2	D00464	40/F	168	112	38	29	109	61	21	31	104	156
3	C95513	40/F	286	227	59	38	181	108	46	80	229	400
4	C94392	31/F	232	202	60	35	156	160	16	23	78	115
5	D004308	45/F	178	111	35	22	105	62	38	30	189	151
6	C098191	40/F	169	117	36	26	93	44	40	25	200	126
7	C098214	40/F	180	132	35	29	120	50	25	21	124	106
8	C96651	50/F	182	156	37	32	118	90	27	19	136	98
9	C97647	30/F	168	140	43	29	79	82	46	40	234	200
10	D000836	25/F	191	135	35	30	144	90	12	11	62	57
11	C099666	37/F	210	186	38	35	145	120	27	33	139	165
12	C97598	48/F	185	169	32	32	134	106	19	34	98	172
13	C098014	32/F	186	137	38	30	101	92	47	25	239	127
14	C099250	47/F	253	219	42	40	182	175	29	33	149	166
15	C95436	44/F	160	106	35	30	113	63	12	11	61	57
16	D000496	38/F	180	178	30	36	120	112	30	68	154	343
17	C098239	38/F	243	238	47	42	112	172	50	28	250	142
18	C97940	48/F	190	147	36	30	117	108	41	27	206	138
19	C94733	32/F	269	218	40	42	185	126	44	34	218	172
20	D000006	32/F	195	190	38	35	109	102	44	40	223	209
21	D000425	37/M	186	149	36	34	130	119	24	25	123	127
22	D000205	48/M	150	138	30	30	102	99	24	39	123	197
23	B55586	26/M	143	136	26	35	94	86	26	45	132	227
24	C96984	50/M	195	178	38	38	116	1256	54	49	274	245
25	D004970	47/M	95	92	19	30	146	40	16	20	83	101
26	C94873	29/M	176	168	30	40	100	79	41	32	206	163
27	C93620	38/M	225	192	45	45	121	119	51	22	258	112
28	C94833	26/F	176	143	29	31	100	86	42	35	212	178
29	C96489	31/F	180	154	54	35	110	80	30	28	122	140
30	C96802	25/F	194	189	29	36	104	86	49	15	249	79
31	4185	48/F	144	140	30	28	101	98	34	31	170	165
32	4228	32/F	150	148	32	28	90	87	24	23	122	120
33	4258	37/F	176	198	35	36	116	96	36	31	184	156
34	4267	42/F	145	140	36	32	77	75	32	30	161	158
35	4251	48/F	134	158	21	30	45	90	27	46	137	232
36	4255	40/F	140	157	24	34	60	75	13	12	67	61
37	4175	42/F	159	200	32	39	117	98	12	35	62	179
38	4226	34/F	211	200	40	38	146	140	21	20	107	102
39	4209	42/F	153	205	32	35	100	96	13	18	66	94
40	5217	26/M	131	128	30	25	70	64	27	24	139	130

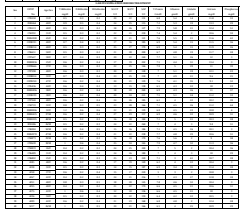
BT-BEFORE TREATMENT AT-AFTER TREATMENT

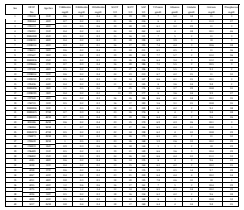
ALL THE 40 PATIENTS ARE NEGATIVE IN CRP AND RA FACTOR

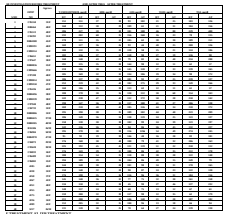












Sl.no	op .no	age	SEX	Albumin		Sugar		Deposits	
				BT	AT	BT	AT	BT	AT
1	C94833	26	F	Nil	Nil	Nil	Nil	2 epi.cells	3 epi.cells
2	C098191	40	F	Nil	Nil	Nil	Nil	3 epi.cells	2 epi.cells
3	D004664	42	F	Nil	Nil	Nil	Nil	1-2 epi.cells	-
4	C95550	36	F	Nil	Nil	Nil	Nil	2-6 epi.cells	2 epi.cells
5	C94392	31	F	Nil	Nil	Nil	Nil	3-6 epi.cells	4 epi.cells
6	C098014	32	F	Nil	Nil	Nil	Nil	1-2 epi.cells 2-4 pus cells	1-2 epi.cells
7	C098239	38	F	Nil	Nil	Nil	Nil	2-4 epi.cells	-
8	D000836	25	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
9	C96489	31	F	Nil	Nil	Nil	Nil	2-5 epi.cells	2 epi.cells
10	C09925	47	F	Nil	Nil	Nil	Nil	-	-
11	4185	48	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
12	4228	32	F	Nil	Nil	Nil	Nil	-	-
13	4258	37	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
14	4267	42	F	Nil	Nil	Nil	Nil	3-5 epi.cells 4-6 pus cells	2-4 epi.cells
15	4255	48	F	Nil	Nil	Nil	Nil	1-2 epi.cells	-
16	4226	40	F	Nil	Nil	Nil	Nil	-	-
17	4208	42	F	Nil	Nil	Nil	Nil	-	-
18	4251	34	F	Nil	Nil	Nil	Nil	-	-
19	4175	42	F	Nil	Nil	Nil	Nil	4-6 pus cells	-
20	5217	26	M	Nil	Nil	Nil	Nil	2 epi.cells	2 epi.cells

URINE INVESTIGATION

Sl.no	Op/ip .no	AGE	SEX	Albumin		Sugar		Deposits	
				BT	AT	BT	AT	BT	AT
1	C94873	29	M	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
2	C96984	50	M	Nil	Nil	Nil	Nil	2-5 epi.cells	2-3epi.cells
3	C93620	38	M	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
4	D004970	47	M	Nil	Nil	Nil	Nil	-	-
5	B55586	26	M	Nil	Nil	Nil	Nil	1-2 epi.cells, 3 pus cells	1-2 epi.cells,
6	D000205	48	M	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
7	D000425	37	M	Nil	Nil	Nil	Nil	2-3 epi.cells	-
8	C099666	37		Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
9	C96651	50	F	Nil	Nil	Nil	Nil	2-3 epi.cells	2 epi.cells
10	D004308	45	F	Nil	Nil	Nil	Nil	1-2 epi.cells	
11	C098214	40	F	Nil	Nil	Nil	Nil	1-2 epi.cells 1-2 pus cells	1-2 epi.cells
12	C97940	48	F	Nil	Nil	Nil	Nil	2 epi.cells	2-4 epi.cells
13	C97647	33	F	Nil	Nil	Nil	Nil	-	-
14	C95513	40	F	Nil	Nil	Nil	Nil	3-6 epi.cells	2-4epi.cells
15	C97598	48	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
16	C94733	32	F	Nil	Nil	Nil	Nil	3-4 epi.cells, 4-6pus cells.	2-4 epi.cells
17	C96802	24	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
18	C95436	38	F		Nil	Nil	Nil	1-2 epi.cells, 2-4 pus cells	1-2 epi.cells, 2 pus cells
19	D000496	36	F		Nil	Nil	Nil	2 epi.cells	2-4 epi.cells
20	D000006	32	F	Nil	Nil	Nil	Nil	1-2 epi.cells	2-4 epi.cells

Sl.no	op .no	age	SEX	Albumin		Sugar		Deposits	
				BT	AT	BT	AT	BT	AT
1	C94833	26	F	Nil	Nil	Nil	Nil	2 epi.cells	3 epi.cells
2	C098191	40	F	Nil	Nil	Nil	Nil	3 epi.cells	2 epi.cells
3	D004664	42	F	Nil	Nil	Nil	Nil	1-2 epi.cells	-
4	C95550	36	F	Nil	Nil	Nil	Nil	2-6 epi.cells	2 epi.cells
5	C94392	31	F	Nil	Nil	Nil	Nil	3-6 epi.cells	4 epi.cells
6	C098014	32	F	Nil	Nil	Nil	Nil	1-2 epi.cells 2-4 pus cells	1-2 epi.cells
7	C098239	38	F	Nil	Nil	Nil	Nil	2-4 epi.cells	-
8	D000836	25	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
9	C96489	31	F	Nil	Nil	Nil	Nil	2-5 epi.cells	2 epi.cells
10	C09925	47	F	Nil	Nil	Nil	Nil	-	-
11	4185	**48**	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
12	4228	**32**	F	Nil	Nil	Nil	Nil	-	-
13	4258	**37**	F	Nil	Nil	Nil	Nil	1-2 epi.cells	1-2 epi.cells
14	4267	**42**	F	Nil	Nil	Nil	Nil	3-5 epi.cells 4-6 pus cells	2-4 epi.cells
15	4255	**48**	F	Nil	Nil	Nil	Nil	1-2 epi.cells	-
16	4226	**40**	F	Nil	Nil	Nil	Nil	-	-
17	4208	**42**	F	Nil	Nil	Nil	Nil	-	-
18	4251	**34**	F	Nil	Nil	Nil	Nil	-	-
19	4175	**42**	F	Nil	Nil	Nil	Nil	4-6 pus cells	-
20	5217	**26**	M	Nil	Nil	Nil	Nil	2 epi.cells	2 epi.cells